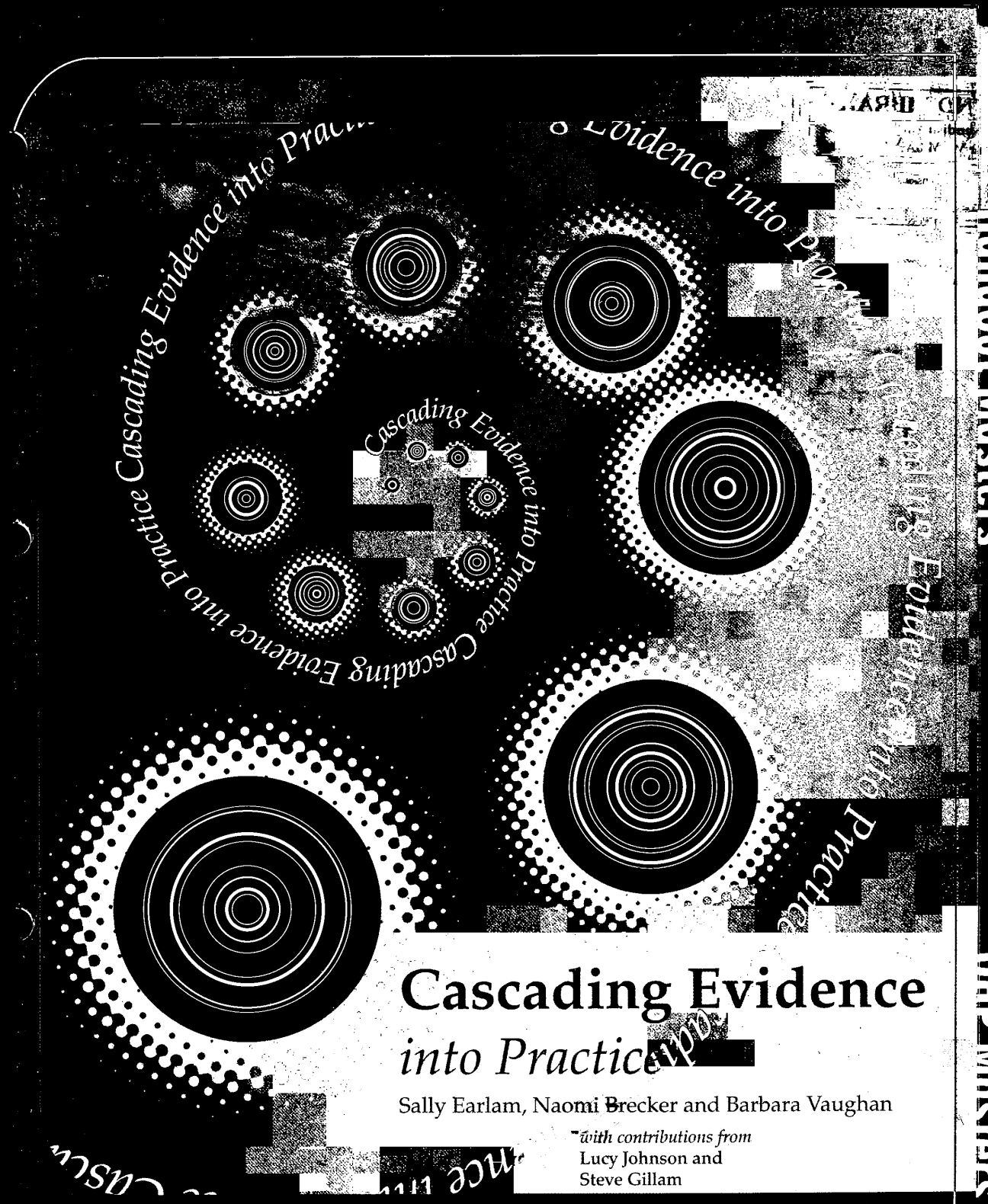

Cascading Evidence
into Practice

Sally Earlam, Naomi Brecker and Barbara Vaughan

with contributions from
Lucy Johnson and
Steve Gillam

King's Fund

A teaching resource pack for healthcare professionals and their educators, bridging the gap between evidence based practice, routes to implementation and managing change for effective practice as required by clinical governance.

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Sally Earlam, Naomi Brecker and Barbara Vaughan

Preface

Increasingly, all health professionals need to be effective 'knowledge managers' – with skills in scanning, appraising and storing new evidence. The advent of clinical governance is already creating a new language. However, the realities of implementation will be more prosaic. Clinical governance leads will lean heavily on the proponents of evidence based practice just as the clinical effectiveness initiative in turn benefited from the learning of health professionals struggling with clinical audit. In both cases, enthusiasm foundered where agendas were seen as too doctor-dominated. In particular, we learnt the need for these new skills, but struggled to get training to those parts of the health service that have ever been hardest to reach.

All the initiatives mentioned are essentially about altering health professionals' behaviour. Multi-faceted approaches are required to change clinical practice. They must appropriately blend educational, administrative and financial incentives. This training pack is designed to help those developing basic skills in evidence based practice. Based on pilot schemes in the field, it is refreshingly multi-disciplinary in approach. The authors are reassuringly eclectic regarding the definition of evidence, as the nature of evidence, particularly in areas of practice that will always elude the randomised control trial, is ever contested. Whatever the promise of this information age, the authors know that the proper measure of such training is its value in practice. Evidence based practice (EBP) will take root if it is congruent with the beliefs and experience of patients and health professionals whose first concern will continue to be humane and holistic care.

Introduction

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This pack has been designed to help people with an interest in, and responsibility for, the development of evidence based practice in line with the clinical governance agenda. The contents have been drawn together following three years' experience of working with small multi-professional groups in order to help them to identify clinical problems which are of local concern. The groups were helped to access and interpret the range of available evidence and, most importantly, to develop and implement action plans in order to change practice.

The pack has been designed so that users can 'dip in' wherever they would like to focus their own learning and/or support that of colleagues. The material is in the form of guidance to teachers who may be leading small groups in clinical or academic settings. The pack has been developed for use by training departments, directorate leaders, ward managers and those personnel responsible for taking the lead on EPB and clinical governance.

Why bother with evidence based practice?

Effective and efficient healthcare, practised in accordance with the best available evidence of what does and does not work, is the ideal towards which the NHS is aiming. There is a strong drive from central government (Department of Health, 1997) which emphasises a fundamental commitment to quality within the health service. In particular, professional accountability for the quality and standard of clinical practice is stressed under the auspices of clinical governance (Department of Health, 1998). All healthcare professionals are required to deliver care which is based on the best available evidence and, where possible, shown to be effective. Similarly, national standards are being developed with an expectation that they will be adhered to locally, in order to enhance the use of effective practice and ensure that ineffective practice is discontinued.

Research and development is another priority area for the NHS. Much effort has been put into quantifying how much research is being under-

taken in health service settings. However, translating the findings from that research into the services delivered is less well developed (Department of Health, 1995). Use of evidence based practice is part of this cycle of events, which encompasses clinical effectiveness strategies and the audit cycle, all of which have a close inter-relationship with the implementation end of the research spectrum.

The manner in which evidence based practice is developed can be seen as a tool to help health service managers and professionals to both assess the value of available research findings (and other sources of evidence) and to ensure the effectiveness of care delivery. The essential steps in the EBP process offer a robust approach to exploring research data by:

- articulating answerable questions
- raising awareness of sources of evidence and efficient means of searching library databases
- ensuring ability to critically appraise the evidence for its reliability, validity, and applicability to a particular service setting
- understanding the possible routes to implementing best evidence into practice, which include change and project management skills.

Successful implementation of change to ensure services are in line with the best available evidence requires the full support of all members of the organisation, including clinicians, managers and support staff, together with an infrastructure that encourages a critical and reflective mode of practice. Library teams and audit support services have a vital role to play, as do the resources which can be accessed through the use of information technology. An increasing emphasis on multi-disciplinary collaboration and high quality seamless care, with the development of evidence based guidelines or care pathways, requires a cultural shift in many healthcare organisations. Evidence based practice, as one of the components of clinical governance, can act as a catalyst to orchestrate that change.

Why now?

If sound evidence is available on which to base practice, this begs the question of why such a drive is needed, or indeed whether those who work in healthcare are responsive to new research findings. Sadly there are many well documented examples of delays in bringing about change when new information becomes available, ranging from a 150 year gap following the discovery that citrus fruit could prevent the occurrence of scurvy before the British Navy made it available for their sailors, to the more recent tardiness in uniform availability of 'clot busting' drugs following heart attacks (Appleby, Walshe & Ham, 1995). A proliferation of published information, together with the lack of time in busy clinical workloads for reading, exacerbates the problem in keeping up to date with the latest research (Sackett, Richardson, Rosenberg & Haynes, 1997). However, an increasing number of

composite and summary sources of high quality evidence provides some short cuts. Many national bodies are developing evidence based guidelines which can be adapted to local use and with the advent of the National Institute for Clinical Excellence (NICE) and National Service Frameworks (Department of Health, 1998), support is becoming more readily available. Demonstration projects such as Promoting Action on Clinical Effectiveness (PACE) also share examples of what can work in the process of changing practice to ensure that well documented evidence is used (Dunning, Abi-Aad, Gilbert, Gillam & Livett, 1998).

Background to the resource

The structure and content of this pack has been based on three years' experience of work between the King's Fund and ten NHS trusts across the north London region. The trusts represented a range of different clinical specialities and settings, with involvement of a variety of different occupational groups including doctors, therapists, and nurses. In some instances managers, librarians and members of audit teams joined sessions enriching the range of ideas and experience which were drawn on.

The aims of the programme, which in piloting ran over a six month period, are to:

- provide a framework and materials for participants to learn for themselves, and with each other, how to structure answerable questions; create awareness of the appropriateness of different types of evidence to answer those questions; develop critical appraisal skills to assess the validity and applicability of the evidence
- teach the principles of project and change management and apply this learning through demonstration projects which focus on issues of local concern
- ensure that the necessary levers for change are harnessed and to encourage the use of the demonstration projects to catalyse further clinical effectiveness initiatives within the organisation
- make available teaching materials which course participants can use within their organisations to cascade the evidence based practice process.

A key feature in development of this work was the collaboration between trust executives, clinicians from a range of different settings and backgrounds and other local stakeholders in order to ensure that the material was sensitive to the local setting. This was achieved through a pre-programme stakeholder meeting to ascertain shared agreement about the purpose of the initiative and commitment to supporting it. Thus the essential components of the programme, namely the basic skills for evidence based practice together with project management and change management, were all set within the overall strategic context of the organisation and were developed with the full support of key managerial and clinical stakeholders.

An outline of the steps taken, which you may find useful to replicate in your training programme, is given below.

1. Preliminary work before starting the programme in order to:
   - ensure senior managers' awareness and support of the programme
   - engage library and audit staff and seek their support in providing local help and expertise
   - identify likely course participants from within the organisation in a position to effect change, where possible, small multi-professional teams
   - identify project areas which could be developed during the course in order to demonstrate the problems, pitfalls and success strategies for identifying robust evidence and implementing changes in practice
   - ensure a common understanding of the strategic direction of the trust/hospital/organisation to clinical effectiveness in order that participants could direct their project work to match the wider needs.
2. Provision of pre-course background reading for participants to familiarise themselves with the purpose of the programme, expectations of their commitment and material for use in the first session.
3. Running six half-day workshops at monthly intervals. These workshops set the context for evidence based practice and taught the principles of project management, change management, the skills necessary for evidence based practice, including critical appraisal, and the routes to implementation.
4. Presentation of the projects to key stakeholders from the trust was held on completion of the programme with an opportunity to set the framework for further evidence based practice initiatives within the clinical effectiveness strategy of the trust.

The course was designed to work incrementally with the best learning achieved by:

- full attendance throughout the course
- individual preparation for each workshop
- participation within project groups with work to be done between workshops
- optional extra assignments for academic accreditation
- participants within each workshop being expected to contribute to working within small groups for experiential learning.

Using this pack

Handout Masters

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While you may wish to replicate the design of the programme outlined, the contents of this pack have been presented in such a way that users can create their own programmes which are sensitive to local need. For example, some users may be familiar with the principles of change management but lack confidence in critical appraisal skills. In this instance they could dip into the sections related to critical appraisal of a randomised controlled trial or a qualitative research article but pay less attention to the guidance offered on change management. Alternatively the pack provides material which could be used as a framework for a multi-professional team to tackle a clinical problem which was of concern to all members. In this instance project management would be a critical component of the programme.

The *Appendix* (page 153) gives some tips on running workshops and training sessions.

Structure of the pack

The pack has four parts. Following the introduction, each part is divided into chapters, each one focusing on the development of a specific skill which is a necessary prerequisite to the introduction of an evidence based culture in practice. Each chapter includes:

- aims and objectives of the session
- training notes related to the topic under discussion
- teaching tips for those who are running the sessions
- exercises and activities
- recommended reading
- overhead projector slide masters for use in the teaching sessions (which may also be photocopied for participants)
- handouts (where applicable)

Photocopiable materials referenced in the chapters are included at the back of the pack.

Note: The slides have also been provided on disc for you to personalise or adapt according to local need or preference. They have been originated in Powerpoint 97. Please refer to your organisation's IT support if you experience problems. Pavilion Publishing and the King's Fund regret they are unable to offer any software advice or support.

Timing

An estimate of the time required for each session has been included at the beginning of each chapter. Most will take about an hour and could be run as stand-alone sessions. Alternatively a series of half or whole day workshops could be offered. Whichever approach is taken, it is worth bearing in mind that the hands-on experience of, for example, using databases to search out relevant material, is fundamental to the success of the learning. While there is an ever increasing number of sources which specialise in searching the literature on behalf on practitioners, these skills are essential in ensuring that the lines of communication between practitioners and information experts are open. Thus time needs to be built in to allow for this additional experience.

It is also worth noting that things always take longer than expected. Our experience of working with the multi-professional teams has shown that:

- most people are over ambitious and try to tackle too big a problem
- most people underestimate the amount of time needed between sessions to allow people to internalise what they have learned or undertake some learning activity between sessions.

Working with multi-professional teams

There is no doubt that there are major advantages to tackling the development of evidence based practice from a multi-professional stance. Expertise of the whole team can be drawn on, project work is more likely to be successful and different members of the team can gain greater insight into the roles and contributions which their colleagues can make.

However, as is always the case, there is a downside to this situation, namely that different members of the teams may have different starting points in terms of what they do and do not understand. For example, while doctors may be very familiar with quantitative studies and randomised controlled trials, they are often much less familiar with qualitative work even though this forms an important part of the knowledge we use when making clinical judgements. This may be particularly overt in the grey areas where there is much less certainty about the knowledge on which practice is based.

In some of the sections we have indicted that it may be necessary to adjust the content according to the learning need of the group. For example, you may need to run two groups at different points in the session, or to harness the skills of some group members to help in the presentation of some sessions with which they are very familiar.

Summary

The material contained in this pack will go some way to helping individuals who have been given the responsibility of developing the use of evidence based practice as part of the whole drive for clinical governance. In sharing our experience we hope that we can help people to cut down on reinventing the wheel in order that their energies can be put into supporting developments in practice.

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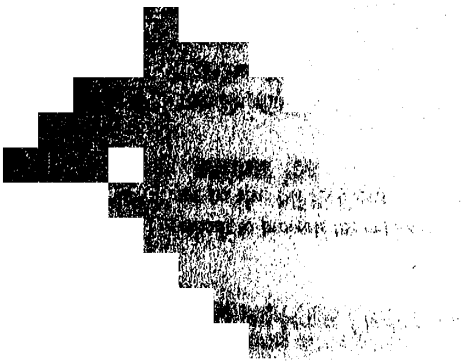


Handout Masters

OHP Masters

Part 1

Getting started with evidence based practice

Chapter 1

Setting the context

Introduction

Over the last two decades, there have been immense changes in health-care, with the focus shifting towards evidence based decision-making for individual patients. That is, trying to ensure that clinical decisions are based on current best evidence and not on, say, tradition.

Aim

- to ensure participants understand the rationale for evidence based practice, setting it within the context of clinical governance.

Objectives

For participants to:

- achieve a common understanding of what evidence based practice entails
- consider why evidence based practice is advocated
- link evidence based practice with clinical effectiveness and show it as integral to ensuring best practice as required by clinical governance.

Timing

Approximately 45 minutes.

Materials

- *Slides 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9. 1.10*
- *Handout 1.1* (enough copies for all participants)
- Flipchart

Handout Masters

OHP Masters

Setting the context for evidence based practice

Quality healthcare, best practice, clinical effectiveness – these terms are commonly bandied around and it is easy to agree with them. There can be little dispute that treatments and procedures shown to be effective should be offered to patients. In addition, ineffective therapies should not be available. But there are many examples where this is clearly not the case.

This has been one of the main driving forces for a change in emphasis on how things happen in healthcare. A move is occurring from reliance on tradition – carrying on with things because that is the way they have always been done – towards clinical decision-making based on the current best evidence of what is effective.

Ideas have been evolving over the last decade and the terminology has changed over that time. ***Slide 1.1*** traces the process. It started as evidence based medicine (EBM) amongst a group of academic physicians, focusing on treatment decisions for individual patients. The randomised controlled trial (RCT) was regarded as the most compelling form of evidence. With time, the strengths of systematic reviews were debated and the methodology refined so that these are now regarded as the 'gold standard' as far as evaluation of interventions are concerned.

Over time, nurses and the Professions Allied to Medicine (PAMs) began to be involved and brought a wider range of questions, including more quality of care issues. The RCT was no longer the only appropriate form of evidence. There was an increasing recognition of the need to match the type of evidence required to the question being asked and the term evidence based practice (EBP) was favoured.

How healthcare is organised is also relevant, and the part which managers play must be recognised. Evidence based practice only presents part of the picture, taking the clinical question as its basis. Clinical effectiveness widens the remit to include the environment and the necessary infrastructure.

You may find *Slide1.1* useful to introduce participants to the different terminology surrounding EBP. It is important that they understand the concepts behind these names, so you may wish to generate discussion around what participants understand by the different terminology.

Clinical effectiveness

The clinical effectiveness strategy for the NHS, as outlined in ***Slide 1.2***, used a tripartite structure – identifying information needs then gathering and appraising the information; steps to change practice; and monitoring the outcomes of those changes. There need to be close links to research and development (R&D) which should be responsive to identified gaps in the evidence. The EBP cycle includes

formulating an appropriate question, then tracking down the available evidence and appraising it for validity, usefulness and applicability. But then mechanisms to foster change are needed if current practice is found not to be in line with current evidence of best practice. Guidelines, care pathways and education are all means that can be used. Monitoring outcomes is important to ensure that any change results in improvements in care and health gain. Audit is a powerful tool for ensuring best practice is followed according to evidence based standards. None of this will work without the necessary organisational infrastructure to support it. This includes time for staff to learn, easy access to information and IT support.

Point out the lists in *Slide 1.2* linking EBP and the research and development agenda under the Change and Monitor headings.

Implementation should result in changing practice.

Why now?

There are a large number of factors that contribute to the promotion of evidence based practice. The major ones are listed in ***Slide 1.3***.

Why now? – 1
Delays in implementing research findings

Delays in implementing research findings into routine practice are common. ***Slide 1.4*** shows some examples of these. The example of citrus juice and scurvy clearly demonstrates that delays are not a new problem. Even so there are still many examples of delayed change in practice occurring today – over 200 years on from the citrus fruit example.

Select one or two examples from *Slide 1.4* to describe in detail (or use an example familiar to you).

- Citrus juice and scurvy
  - 1601 First experimental data of efficacy
  - 1747 Findings confirmed
  - 1795 Routine use of lemon juice by British Navy

- Thrombolytic therapy in acute MI
  - 1973 Good evidence for reduction in mortality
  - 1982 First meta-analysis
  - 1986 Only recommended for routine use in half of expert reviews and text books
  - 1990s Not always received in timely fashion by patients who would benefit

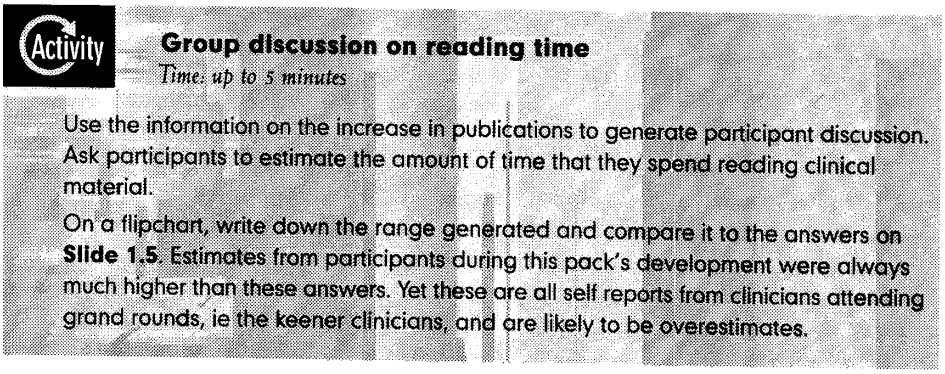
- Steroids in pre-term labour
  - 1972 First controlled trial
  - 1990 Meta-analysis
  - 1995 Uptake still poor

- D & C in under 40s
  - 1993 Despite being shown to be therapeutically useless and diagnostically inaccurate, still the fourth most commonly performed surgical procedure in the NHS in 1993

Why now? – 2
Growth of information

Another reason for the current interest in evidence based practice is the rate of growth of biomedical journals. The *British Medical Journal*, the *Lancet* and a few other journals were first published in the 1850s. Since then, there has been an exponential growth in new titles. In 1900 there were 400 titles published; by 1992 this had risen to 7,500.

Professor Sackett, one of the leading proponents of evidence based medicine, has highlighted one of the problems in trying to keep up-to-date – the time required for reading. It has been estimated that a GP needs to read 19 articles a day, 365 days a year to keep abreast of the literature. At present there is no comparable estimate for nurses or professions allied to medicines.



Why now? – 3
Decline in best care knowledge

The sheer amount of information available and the limited time to digest it, makes it no surprise that knowledge of current best care has a negative correlation with years

since graduation, sometimes known as the slippery slope, ie the longer it is since graduation, the poorer a person's knowledge of best practice. This was based on data collected in Canada using a multiple choice questionnaire testing physicians on their knowledge of treating hypertension.

Why now? – 4
Variations in practice

Variations between regions

The next consideration in the factors moving us towards EBP is the variations in health and in access to healthcare. For example:

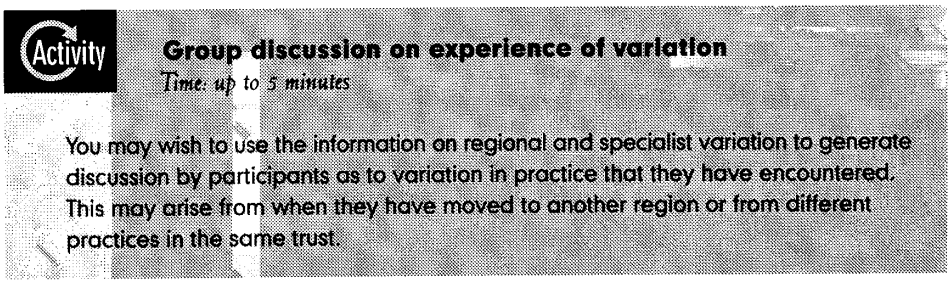
- the death rate from coronary heart disease in people younger than 65 is about 3 times higher in Manchester than in west Surrey
- the proportion of women aged 25–64 screened for cervical cancer varies from 67% to 93% in different areas of the country
- the number of hip replacements in people aged over 65 varies from 10 to 51 per 10,000 of the population.

(*Department of Health, 1997*)

Variations between practitioners

Variation not only occurs between regions, but also between specialists, consultants and GPs within the same region. For example:

- the regional variation for tonsillectomy and adenoidectomy is from 14 to 25 per 10,000 people
- the specialists variation is from 46% to 86% of children seen as outpatients
- the regional variation for hysterectomy is from 27.1 to 47.3 per 10,000 women aged between 20–74
- the variation between GPs in one town was between 12 and 37 women for every 10,000.



Handout Masters

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Why now? – 5
Consumer pressure

Consumer pressure is also growing. Patients have easier access to information, for example through the internet and through the increasing number of patient groups. Some patients want to take part in treatment decisions, and there is a greater pressure on practitioners to be up to date with evidence of best care.

Why now? – 6
Political initiatives

We now turn to perhaps the strongest driving force: that of political initiatives. Clinical effectiveness has been highlighted by governments since 1993. It became a medium term priority in 1995 and culminated in the White Paper in December 1997 (Department of Health, 1997). The following are three quotes from the White Paper. The first two quotes show the perceived importance of EBP. The third quote introduces the concept of individual accountability for the quality of decision-making. The term coined for this is **clinical governance**.

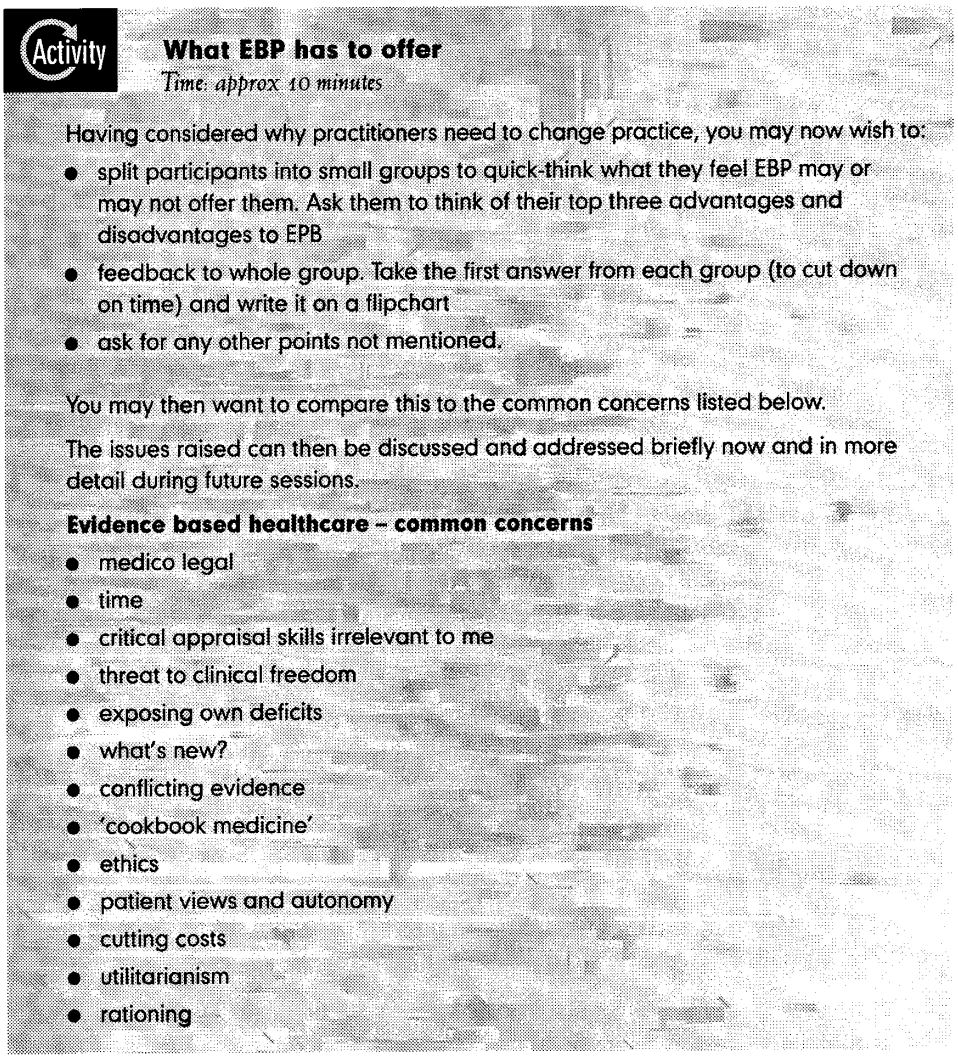
- 'The Government is determined that the services and treatment that patients receive across the NHS should be based on the best evidence of what does and does not work'
- 'A quality organisation will ensure that evidence based practice is in day-to-day use with the infrastructure to support it'
- 'Shifting the focus towards quality will require practitioners to accept responsibility for developing and maintaining standards'

Clinical governance

A definition of clinical governance is given in ***Slide 1.6***. The chief executive of an organisation will carry the ultimate responsibility for the quality of clinical decision-making within the organisation. This is likely to mean that organisations will provide evidence based accountability frameworks for individual clinicians.

Slide 1.7 shows the headings, taken from the Department of Health's *A First Class Service: Quality in the new NHS*, published by The Stationery Office in 1998, which are expanded on in ***Handout 1.1 – Main components of clinical governance***.

It may be helpful to ask the person with a lead for clinical governance in your local trust to contribute to this session.



Evidence Based Practice – skills required

Once participants understand the rationale for EBP, it will be time to move on to teaching the skills required to be able to practise it. The steps used in evidence based practice are outlined in ***Slide 1.8*** starting with 'Asking answerable questions'. Clinicians need to be familiar with all these skills to ensure that evidence gets into practice.

The Venn diagram in ***Slide 1.9*** shows that EBP is about combining:

- the best available external clinical evidence
- individual clinical judgement/expertise
- patient choice – a point that is sometimes forgotten.

It is important that the sole focus does not fall on research evidence alone.

EBP needs a multi-disciplinary approach

The final point to be made is that EBP needs a multi-disciplinary approach. To achieve a quality service, doctors, nurses, PAMs, pharmacists, managers (everybody in the health service) need to work together. Improving just one area of practice is unlikely to make much impact on patient outcomes.

In conclusion, *Slide 1.10* recaps on where evidence based practice sits in the current NHS. Best evidence of effective care is only one of the steps towards clinical governance. This has to go hand in hand with managing change to ensure evidence is implemented to ensure there is accountability within the health organisation for quality care.

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Chapter 2

Asking answerable questions

Introduction

Faced with a plethora of problems and a wealth of published (and unpublished) information, accessing the evidence may seem like a daunting task. Careful thought as to what it is one wants to know will reduce the search time and maximise the chances of identifying appropriate material.

The starting point for evidence based healthcare is to identify clinically relevant and important issues. The next stage is to write a well-structured question that will facilitate database searches.

Aim

- to appreciate the importance of posing clinically relevant, well-defined questions before accessing evidence.

Objectives

For participants to:

- understand the derivation and purpose of the PICO structure as a framework for defining clinical questions, and recognise its limitations
- feel confident about generating a four-part question from a clinical scenario.

Timing

Approximately 45 minutes.

Materials

- *Slide 2.1*
- *Handouts 2.1, 2.2, 2.3, 2.4, 2.5* (enough copies for all participants)
- Flipchart

Handout Masters

OHP Masters

Asking answerable questions

Poorly defined questions

Time: approx 5 minutes

This activity takes the group through a process which moves from broad, ill defined issues to tight, clearly defined questions.

1. Set the task by asking a poorly defined question, such as:
   - does health promotion work?

   or
   - what is effective in accident prevention?
2. Working in small groups, participants should jot down:
   - ideas as to why it would be difficult to search databases for material to answer the question
   - what more specific information would be helpful.

Discussion

Having clarified that the question is too broad and vague, ask the group to quick-think what the components of a well-phrased question are.

Record responses on a flipchart, facilitating the group to generate the PICO nemonic:

P who or what is the patient/population/problem?
I what intervention is being considered?
C what is it being compared with?
O have the anticipated outcomes been defined?

PICO in more detail

Professor David Sackett from the Centre for Evidence Based Medicine in Oxford, together with colleagues W. Scott Richardson, William Rosenberg and R. Brian Haynes, have promoted the use of the four-part PICO structure as the basis for formulating an answerable question (see ***Slide 2.1***). You can use this slide to take participants through the key steps in the PICO method (middle column of the slide). Then the example in the third column can be used to demonstrate how the formula works. (You might wish to vary the example to complement the clinical background of your participants.)

The PICO steps

1. Identify the *population* of interest by asking, 'How would I succinctly describe a group of similar patients?' Factors that might need to be considered include age, sex, patient settings, suffering from certain symptoms or asymptomatic, etc.

2. Consider the *intervention*. This can include tests, treatment or a process of care, and is used to describe the main action that is being considered, eg drug therapy, x-ray, screening test, counselling, education.
3. Next the *comparison* states what is/are the other options or alternatives that could be offered to the patient.
4. Identify the *outcomes* that you and the patient consider to be of primary importance, eg survival, quality of life, being able to continue certain hobbies and so on.

You may wish to ask participants to generate examples of the four steps in order to ensure they have understood the method.

The two areas where misunderstandings often arise are around the broad interpretation of 'intervention' and what 'outcomes' are.

Generating questions

A series of scenarios for the groups to choose from are given on **Handouts 2.2** to **2.5**, or you may wish to generate your own scenarios around relevant clinical fields. **Handout 2.1** outlines how to go about this exercise.

1. Arrange participants in groups of two or three. Distribute one copy of each handout to every participant.
2. Ask the groups to generate a structured question from their chosen scenario. This can be from the perspective of the patient, the practitioner, or both.
3. Ask the group to write their question onto a flipchart to share with the whole group. Allow about 15 minutes for this.

There are a number of different questions that might be asked of each scenario. Encourage discussion around this, including the importance of being clear about which outcomes are relevant.

Uses and limitations of PICO

The session may be drawn to a close with a discussion on the uses and limitations of the PICO structure for defining answerable questions.

The bias toward interventions in PICO can be pointed out; it may not always be appropriate to specify an intervention, but the population group and outcomes can still be identified. PICO also has some limitations in framing questions which can best be addressed through qualitative research which focuses on processes rather than outcomes.

Complex cases

'Many aspects of management in primary care, care of older people and chronic medical conditions do not lend themselves to the formulation of single answerable questions or the application of discrete, definitive interventions.'

Greenhalgh, T. (1996) Is my practice evidence-based? *British Medical Journal* **313** 957–8

For complex clinical problems as described above, all the component issues need to be mapped out and then a succession of structured questions framed to deal with each issue. Participants might be referred to decision analysis as a model for this.

There is a plethora of different research methods to address the complex questions in healthcare. For example, while randomised controlled trials are the gold standard for assessing the efficacy of specific clinical interventions, qualitative research gives insight into *why* people behave as they do.

You could refer here to ***Chapter 4 – The nature of evidence.*** A variety of different types of outcome are relevant and important to healthcare – evidence is not just about health improvement but may also include palliation, satisfaction and quality versus quantity of life.

Participants could also be referred to ***Chapter 15 – Outcomes in healthcare.***

Further reading

Greenhalgh, T. (1996) Is my practice evidence-based? *British Medical Journal* **313** 957–958.

Greenhalgh, T. (1997) *How to Read a Paper: The basics of evidence-based practice.* London: British Medical Journal Publishing Group.

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Chapter 3

Search strategies and sources of information

Handout Masters

OHP Masters

Introduction

As outlined in ***Chapter 1 Setting the context***, we are moving towards a healthcare system that should be based on best evidence. The next problem to address is how to find this evidence.

The first place to start should always be the research literature. This is usually most efficiently accessed through electronic databases.

This session demonstrates search strategies that can be carried out on Medline, the database of the National Library of Medicine (NLM) in the USA. We have chosen Medline since most work on effective search strategies has been done on this database. Unfortunately there is little published work on other healthcare-related databases, and it can be hard to find all relevant research. If you make use of other databases and the papers are not very forthcoming, your search for evidence may need to be wider, eg by speaking to experts in the field. However the principles of searching databases remain the same, whichever source you use.

Aims

- to explain how to search for evidence to inform clinical effectiveness
- to describe the different sorts of information available
- to introduce some of the most important databases.

Objectives

For participants to:

- put the need for searching skills into the context of medicine and clinical research

- describe how a search question needs to be broken down so that it can be used scientifically and searched on effectively
- describe some of the databases available for searching
- give some examples of searches using those MeSH (Medical Subject Headings) terms which can be used when hunting for the evidence.

Timing

Approximately 45 minutes.

Materials

- *Slides 3.1,3.2, 3.3, 3.4*
- *Handout 3.1* (enough copies for all participants)
- Flipchart

It may be useful to involve a local librarian in this session, so they can let participants know what is available locally.

The vastness of the information

There is a vast amount of information available to clinicians and health service managers, which comes in many forms and is of hugely varying quality.

It also loses currency more quickly than information in many other professions.

The evidence consists of:

- vast quantities of papers...
- ...which are produced in many forms...
- ...which are of varying quality...
- ...whose contents go out of date very quickly.

Out of date evidence

Thousands of articles are added each year to this body of information. Of these, many will be out of date in a few years. In *How to Practice and Teach Evidence-based Medicine*, it is said that a medical school dean is reputed to have said to a graduating class:

'Half of what we have taught you won't be true in 5 years. Unfortunately, we don't know which half.' (Sackett *et al.*, 1997)

Identifying what is relevant

Not only is the body of evidence ever growing, but also the validity credited to individual papers changes over time. Having access to information is not enough. One needs to identify the relevant texts. For this, you need both effective searching skills and evaluative skills.

Lack of reading time

Clinicians and other healthcare workers have little time to read the information they have. Sackett *et al.* (1997) calculated that the amount of time that clinicians spent reading in any one week varied from a maximum of two hours for a medical student to perhaps as little as 20 minutes or even none for house officers. Once medical students leave university, their reading time decreases dramatically. For instance, in the survey, consultants graduating before 1975 spent between 10 and 45 minutes a week reading, but 40% of those questioned reported no reading at all in the week prior to the survey. It is also worth bearing in mind that this reading will only be of those journals to which the clinician subscribes or has library access. There is no way of covering all the published information.

General sources of evidence

Published information itself is only part of the body of evidence on effectiveness. There are many other sources which can be tapped (***Slide 3.1***). Grey literature refers to information that is not published in the form of a conventional book or journal article (eg internal reports) and which is not easily accessible. Not all of these types of information will be useful when searching for effectiveness material. However, it is possible to find at least some of the useful papers via electronic databases.

Filtering out

So what sort of information is wanted? Out of this array of evidence only the most rigorous is usually needed when planning best patient care. This means filtering out certain items (***Slide 3.1***).

So, how does one go about finding all this effectiveness information? First of all, it is necessary to know quite a lot about the subject in question.

Revision exercise: PICO

You may feel it is worth quickly recapping on the PICO method that was covered in *Chapter 2*. If so:

1. **Ask the participants to recall what PICO stands for (patient, intervention, comparison, outcome).**

2. **Then ask them to formulate a PICO framework. For example, one might want to conduct a search on the effectiveness of nicotine patch therapy on giving up cigarettes.**

The question might end up as:

P Patients aged between 35 and 45 who have presented at a GP surgery. Known smokers, who say they want to stop smoking

I Nicotine patches

C Health education alone

O Cessation of smoking (long term); weight gain; irritability; reduction in breathlessness.

Do patients aged between 35 and 45, who have presented at a GP's surgery, are known smokers but want to stop smoking, have better long-term smoking cessation using nicotine patches than those who only receive health education?

3. **As it stands this search is not yet exact enough to perform. Ask the participants what they may want to know about:**
   - **the patient population**
   - **the intervention**
   - **comparisons**
   - **outcomes.**
4. **The group's answers are probably best put up on a flipchart or similar aid.**

Looking at databases – specialist review sources

Once the question has been formulated, the next step is to look at the available databases. Some of the sources available for finding evidence of effectiveness are listed in ***Handout 3.1***.

Give this out and briefly run through the sources with the group.

The first port of call should be the specialist review sources, mainly produced by the Cochrane Centre and the NHS Centre for Reviews and Dissemination (CRD). Almost all of these are available on one CD: The Cochrane Library, which is available in most medical and nursing libraries.

Cochrane Database of Systematic Reviews (CDSR)

The CDSR contains full-text systematic reviews on many topics. It also provides the tabular meta-analysis information used to inform each review.

Cochrane Controlled Trial Register (CCTR)

The CCTR is a register of published RCTs and contains over 150,000 trials. All the trials it contains have subsequently been re-indexed on Medline, irrespective of whether the journals in which they are located are routinely indexed on Medline or not.

Database of Abstracts of Reviews of Effectiveness (DARE)

DARE is produced by the CRD; it complements CDSR by giving information on systematic reviews in the form of structured summaries and critical appraisals. It also includes abstracts from other places such as the ACP Journal Club. Some of the abstracts will not have met the CRD guidelines but will still have been included as they contain useful background information on a particular topic.

Centre for Reviews and Dissemination (CRD)

The CRD also produces the NHS Economic Evaluation Database (NEED). This is only available via the Web and not on the Cochrane Library. It critically appraises articles which discuss the cost-effectiveness of specific interventions.

Other sources

Once these sources have been exhausted, other sources could then be turned to bearing in mind however, that one good systematic review from Cochrane could be worth many smaller studies found elsewhere.

Other types of database are of two types:

1 general healthcare sources
2 subject specialist sources.

General healthcare databases include the following:

- Medline
  The database of the National Library of Medicine (NLM) in the USA
- Cinahl
  Covers nursing and social sciences
- Embase
  Produced by Elsevier and contains medical and pharmaceutical information.
- HealthSTAR
  Also produced by the NLM and contains information on health systems management and planning
- SCISEARCH
  The Science Citation Index
- DH-Data
  The database of the Department of Health in the UK

Subject specific databases include:

- CancerLit
- PsychLit
- AIDSLine
- Toxline

Yet more sources...

Once these more traditional sources have been exhausted, other, perhaps less obvious sources of information could be used, such as:

Journals

- Evidence Based Medicine
- Evidence Based Nursing
- ACP Journal Club
- Bandolier – available on the Web

Centre for Reviews and Dissemination (CRD)

- Effective Healthcare Bulletins
- Effectiveness Matters
- AHCPR guidelines – available only on the Web

CD-ROMs

- Best Evidence. This has over 1,000 structured abstracts and commentaries on it from the ACP Journal Club (since 1991) and Evidence Based Medicine (since 1995).

It becomes clear how many and varied are the places in which one can hunt for written evidence. Their number is also growing and it is necessary to keep an ear to the ground to find out more.

Web sources

Andrew Booth's paper, *Netting the Evidence*, is an excellent resume of many available sources of evidence on the Web. See www.shef.ac.uk/uni/academic/R–Z/scharr/ir/netting.html.

The Scharr Guide to Evidence Based Practice is also a good guide to other sources of evidence and is available on the internet. See www.shef.ac.uk/uni/academic/R–Z/scharr /ir/scebm.html.

Medline

It is important to reiterate the need to look in many places. Medline is very useful but it is not the only place where effectiveness information is located. In fact it comprises only a small part of the body of evidence. Dickersin and Herxheimer (1996), report a test to discover the sensitivity or recall of Medline when searching for RCTs on vision from the late 1980s. They found a gold standard of clinical trials which included all known RCTs published in journals, both those indexed in Medline and those not indexed there. They then reviewed how many of these were retrieved from Medline. They concluded that, using this gold standard, the sensitivity of Medline was 51%, ie Medline retrieved only 51% of the references. This piece of work was undertaken in order to inform systematic reviews, but it helps to see that about half of all RCTs will be omitted at the start if a search is restricted to Medline alone. The contents of Medline constitute only a small part

of the entire body of evidence. That said, Medline is often the first, albeit not the only, place to go for effectiveness information.

Filters: using Medline to find RCTs

Filters are search strategies which are run again and again to hunt for certain types of references. The filters in ***Slide 3.2*** are taken from the work of Barbara Cumbers and Reinhard Wentz (1997) as a guide when looking for RCTs in Medline. An explanation of the symbols commonly used is given below.

It is important to use both MeSH terms (*Medical Subject Headings*, a thesaurus which all Medline search systems include) and publication types in order to cover all possibilities and ensure all items are retrieved, even though they may have been indexed in slightly different ways.

Medical Subject Headings

Those terms which come from the MeSH thesaurus are identified by a forward slash (/) suffix (eg controlled clinical trials/). These terms will appear in the subject headings field. You need to consult the thesaurus in order to identify which terms are in MeSH. The thesaurus is often available in electronic form with Medline.

Publication type

Another field which is important to search is the publication type. Appending the tag.pt. hunts for terms in this field (eg randomised controlled trial.pt.). This field describes the type of reference to which the record relates. Another example of a publication type would be meta-analysis.

Textwords

One can also hunt in the title and abstract of each record by searching for textwords. This is done by appending the tag.tw. after the chosen terms (eg placebo$.tw.). The dollar sign ($) simply truncates the term so that any records containing words which begin with the seven letters 'placebo' (such as 'placebos' as well as 'placebo') will be returned.

Using Medline to find systematic reviews

As some references may have been indexed in Medline in slightly different ways it is important to search in many fields in order to ensure that as many relevant items as possible are retrieved. It is also often necessary to search for the same terms in a variety of fields. In the example given in ***Slide 3.3***, the term 'meta-analysis' is hunted

for in the publication type field (using the .pt. tag), in the subject headings field (using the / suffix to show that it is a controlled, thesaurus term) and in both the title and abstract fields (using the .tw. tag to look for it as a textword).

This filter can be used to find systematic reviews, meta-analyses, review articles and other articles which may have slipped through the indexing net but which may refer to double-blind or triple-blind techniques. It will exclude those which are simply chatty editorials.

Filters such as these can be saved as search strategies or search histories on the PC which holds the Medline database, and used again and again.

Please note that if you use Medline with different software (for example SilverPlatter) you will still be able to use these strategies but the searching syntax will be different. You should consult your software's help screens to ensure you are searching in the same fields as shown above.

Once a filter has been applied, additional subject specific MeSH terms and textwords should then be used to narrow the search down to the subject of interest. Using MeSH with textwords is the strongest searching combination.

Narrowing a search

Time: approx 3 minutes

This is the point where using the PICO formula can help by narrowing your results down to a reasonable number. Carrying on in the vein of smoking cessation used earlier, the terms below could be used to find evidence on the effectiveness of nicotine replacement patches.

You could ask the group to quick-think these and note them on a flipchart. Identify any missed out.

1 smoking/
2 smoking cessation/
3 nicotine/
4 (nicotine adj replacement).tw.
5 patches.tw.
6 5 and (4 or 3 or 2 or 1)

Joining different sets of search results

Once you have two or more sets of results, they can be joined as in **Slide 3.4**. In this case, we have the set of results which relates just to RCTs or systematic reviews and the set which relates to smoking cessation. The combination should return a reasonable number of records.

Summary

At this point, evaluative and critical appraisal skills will come into play to weed out those few references which do not look as relevant, but the process of obtaining the full set of references has certainly been simplified by employing the filter in the first place.

The construction of a search question, the judicious choice of databases and the employment of the MeSH filters should go some way to reducing the mountain of information available to something much more manageable, highly relevant and scientific.

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Walker-Dilks, C. J., McKibbon, K. A., & Haynes, R. B. (1994) Beyond ACP Journal Club: how to harness Medline for etiology problems. *ACP Journal Club*. Nov–Dec 121 A–10.

Walker-Dilks, C. J., McKibbon, K. A., Haynes, R. B. & Wilczynski, N. (1995) Beyond ACP Journal Club: how to harness Medline for prognosis problems. *ACP Journal Club*. Jul–Aug 123 A–12.

Handout Masters

OHP Masters

Chapter 4

The nature of evidence

Handout Masters

OHP Masters

Introduction

The knowledge we draw on to inform our decision-making in all walks of life, is complex and multifaceted, arising from a range of different sources and experiences in our pasts. To a large extent, what we accept as important or even legitimate knowledge is influenced by our backgrounds. As Allen (1985) says:

'...actual knowledge is always limited in some sense by the socio-historical context in which it arises.'
Allen, 1985

In this sense, we can only understand things within the context of our own backgrounds and we will, in turn, be influenced by what is important to us, by what we value and by what matters.

Aims

- to explore the range of knowledge which may influence clinical decision-making
- to introduce the research methodologies employed.

Objectives

For participants to:

- have an insight into the range of sources of knowledge
- give a considered view of what is legitimate evidence for specific questions
- be able to identify basic research designs
- acknowledge variations in health professionals' approach to research.

Timing

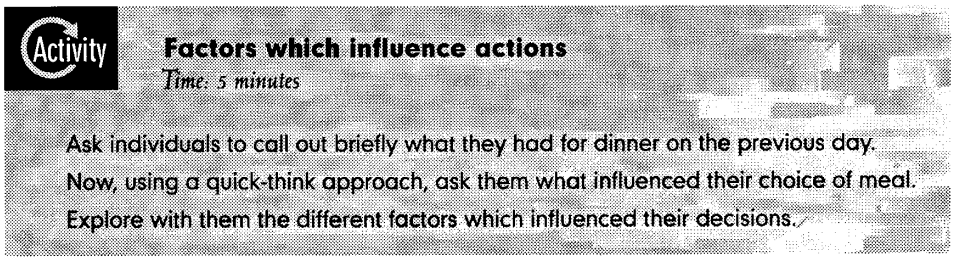
Approximately 1½ hours.

Materials

- ***Slides 4.1, 4.2, 4.3***
- ***Handouts 4.1, 4.2, 4.3*** (enough copies for all participants)
- Flipchart

Sources of knowledge

Pulling out the sources of knowledge we use in everyday life can help to demonstrate the range of factors which influence the way in which we behave.

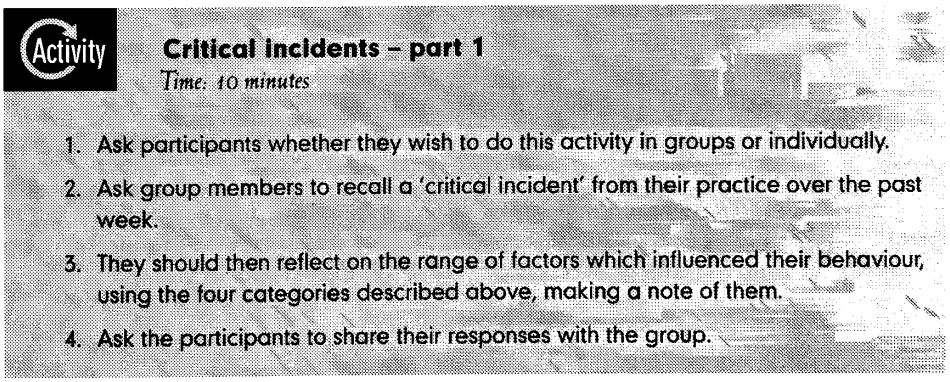


This is a simple way of demonstrating the different factors which influence all our actions. It is a lighthearted activity and, as such, should not be too drawn out, but it can be a powerful way of making a point.

Types of knowledge

It is helpful to have some framework which will help people to classify the knowledge which they commonly use. One such framework is that offered by Carper (1978). She suggests that in all decision-making there are four basic types of knowledge namely: empirical, ethical, aesthetic, personal.

Distribute ***Handout 4.1*** and allow a few minutes for participants to read through it.



Handout Masters

OHP Masters

It is worth spending a bit of time ensuring that group members have an opportunity to explore the range of different factors which influence them personally, in order to help them to gain insight into the different ways in which knowledge may be developed.

Note: This exercise can be undertaken within the workshop or outside it. If the activity is done outside the workshop, participants will need to keep a brief written record of their thoughts, to bring back to the next group meeting.

World views of knowledge

Approaches to knowledge development

Having highlighted the different sources of knowledge the next question to be addressed is the range of different approaches to gathering knowledge. Classically there are three 'world views' each of which will use a different approach to the gathering of knowledge:

1 positivism

2 naturalism

3 critical social theory.

Distribute *Handout 4.2* and allow a few minutes for participants to read it. The approaches will now be discussed in more detail.

Critical Incidents – part 2

Ask participants to return to the critical incidents which they identified in the earlier group/individual work.

Then ask them to identify which of the three world views of knowledge would be most suitable to expand their understanding of the issues affecting the critical incident.

It is likely that a number of different questions will be raised in relation to the critical incident, each of which may be addressed from a different perspective, using a different 'world view'.

Spectrum of evidence

Historically there has been a professional bias in favour of the quantitative approach, seeing it as providing the best evidence. This may partly be because it is conceptually easier to understand and use. It also brings a greater degree of certainty into the lives of practitioners (***Slide 4.1***).

Healthcare, however, needs a combination of both qualitative and quantitative research to enable professionals to deliver best care.

Using the best available evidence

Evidence based practice is about tracking down the best available evidence with which to answer a question. What 'best available' is will vary according to the question asked.

You may look for an experimental, quasi-experimental, or qualitative design. You may also wish to gather opinion-based evidence to add to your information. The issue is to try to elicit the fullest range of knowledge possible.

Clinical research designs

There are six main clinical research designs which are commonly employed to add to our body of knowledge (***Slide 4.2***.). These include methods suitable for numerical analysis, and those which encompass approaches to help us grasp the complex meanings involved in healthcare. They are:

- randomised controlled trials
- cohort studies
- case-control studies
- cross sectional study
- qualitative research
- systematic review or meta analysis.

A brief overview of each is in ***Handout 4.3***. More details can be found in the relevant chapters in ***Part 2*** of this pack.

Distribute ***Handout 4.3*** and allow a few minutes for participants to read it.

Clinical research designs

Time: 15 minutes

Using the questions generated from the critical incidents used in the previous activities, break into small groups and ask each group to consider how they may ascertain the best evidence in relation to the questions posed is **Slide 4.3**.

This activity may generate some debate among the group about the manner in which the questions are framed and whether, in order to get a fuller picture, more than one approach could be used.

References

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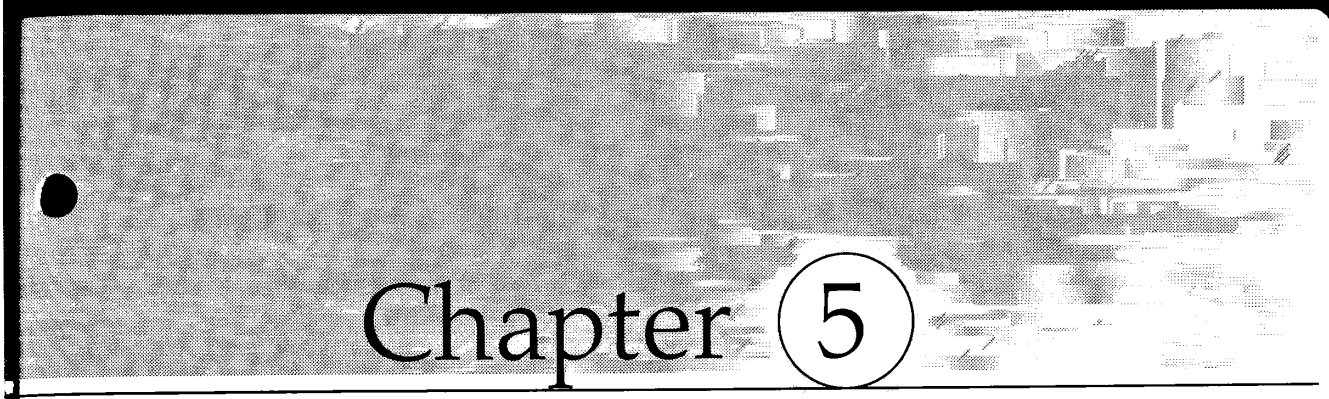
Handout Masters

OHP Masters

Part 2

Critically appraising the evidence



Chapter 5

Randomised controlled trials

Introduction

A randomised controlled trial (RCT) is a scientific research method which is used to compare one approach to treatment with another in order to find out which one has better outcomes. It is commonly used to assess the value of a new method of treatment such as:

- a specific drug regime
- home versus hospital care
- a well defined way of managing a leg ulcer.

Purpose and design of RCTs

The purpose of RCTs is to eliminate or minimise bias. This is achieved by randomly allocating eligible patients to receive one of:

- the new treatments
- the standard therapy or the placebo.

All groups are followed up in an identical manner, measuring a small number of predefined outcomes.

The two groups are referred to as the experimental group and the control group. Through random allocation, the groups are matched for any other factor which may influence the outcome such as age, gender or disease. Inclusion criteria, which are defined at the outset of the trial, limit the number of people who may be invited to take part in the trial.

Uses and limitations of RCTs

Randomised controlled trials are considered by some to be the gold standard for finding answers to clinical questions relating to interventions. They are mainly concerned with treatments or prevention. However, RCTs have some limitations in their clinical value. For example, the strict selection criteria of participants may not be representative of other local populations. A well designed RCT should only look for one or two main outcomes. This is necessary in order to reduce the likelihood that any result has occurred due to chance. This means a lot of data which may be pertinent to an individual may not be included in the analysis.

For these reasons it is important that results from an RCT are critically appraised to assess their validity and applicability in alternative settings, before implementing the findings.

Aim

- to help participants to gain confidence and skill in reading and appraising reports of randomised controlled trials.

Objectives

For participants to know:

- what makes a good randomised controlled trial
- the importance of bias and chance in research
- basic statistical concepts used in analysis of randomised controlled trials.

Timing

Approximately 1 1/2 hours.

Materials

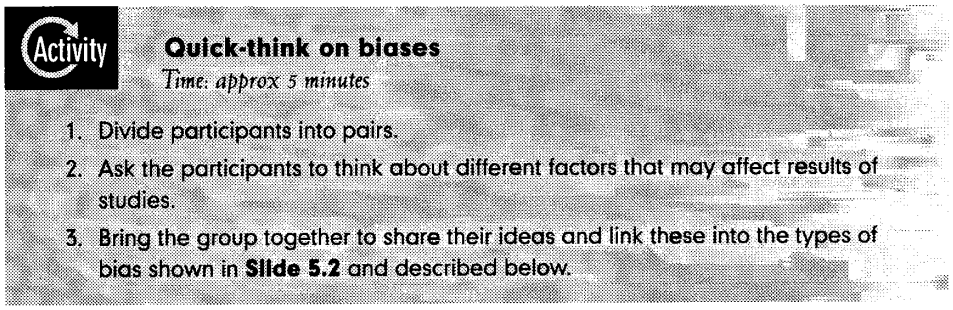
- *Slides 5.1, 5.2, 5.3, 5.4, 5.5*
- *Handout 5.1* (enough copies for all participants)
- Flipchart
- An opaque bag containing 2 different types of sweet (same size and shape) for the group work on sampling. There should be three sweets per participant.
- Your choice of paper to be critically appraised – copies for all participants (see Activity on page 50).

Randomised control trials

Show ***Slide 5.1 – randomised controlled trials.***

Use this to introduce:

- a discussion about the relative value of data gathered using observation, compared to that gathered through scientific research, particularly in terms of susceptibility to bias
- the purpose behind random allocation with aims of eliminating or minimising bias, which in turn can influence results of research.



Types of bias

Selection bias

Selection bias occurs when the researcher (often subconsciously) places the fitter patients into the new treatment arm.

Measurement bias

Measurement bias occurs when either the researcher or the patient perceives the outcome on the new treatment to be better, as we are all inclined to think that new *must* be better.

Confounding bias

Confounding bias occurs indirectly, ie not as a direct result of the treatment, but for some other reason. For example, if a drug tastes nasty, compliance may be poor. If the taste were changed, compliance might improve and the results might be different.

It may be necessary to give some group members help in identifying some forms of bias. It would be useful to have a few examples ready to share. It may also be useful to again emphasise that randomisation is used to help eliminate biases.

Discussion of RCT methodology

Time: 30 minutes

1. Divide the participants into small groups.
2. Give them the scenario that a new drug for the treatment of rheumatoid arthritis has been developed. It has been decided that a study needs to be conducted to see if the new treatment is in fact better than the old treatment.
3. Ask the groups to think about how they would go about setting up a study.
4. Take group feedback, linking their thoughts into the seven steps shown on **Slide 5.3**. Randomised controlled trials classically follow a clearly defined pathway as shown in **Slide 5.3** and described below.

The seven steps

1. Defining the hypothesis

Once an area of equipoise has been identified, a hypothesis is generated in order to identify the question that is to be answered. It is at this point that an estimate of sample size is made. As a rule of thumb the greater the likelihood of an outcome being found by chance, the larger the sample size needed to gain a degree of certainty in the outcome. Thus the sample size will vary with expected variations in outcomes between the two groups.

2. Selection

Inclusion criteria and exclusion criteria are set to allow selection of appropriate patients. (This can be linked back to the previous exercise on bias.)

3. Informed consent

Informed consent is usually required. This may be written or verbal. There are many issues around consent, including how you address different patients' needs about the amount of information they want, and can synthesise.

4. Entry

Patients are then entered into the trial and, for the purpose of the analysis, will remain on the trial. This does not affect their rights to stop or change treatment at any time.

5. Random allocation

The method of randomisation will have been agreed previously and is ideally controlled by a computer programme to minimise risk of inadvertent bias.

6. Treatment

Patients will then receive the treatment they have been allocated .

7. Comparison of outcomes

Statistical analysis is used to ascertain whether the new treatment is better, worse, or no different to the control group. Analysis should be based on what is known as 'intention to treat'. Even if patients stop or swap treatments, they are analysed in the groups that they are initially randomised to. In critical appraisal it is important that all patients entered onto the trial are accounted for.

RCTs are frequently represented diagrammatically in trial proformas and published papers. A typical format for these diagrams is shown in ***Slide 5.4***.

Types of trial

Trials may be:

- **blind** – when either the patient or the clinician does not know which treatment the patient is receiving.
- **double-blind** – when neither know.
- **pragmatic** – where it is felt that the knowledge of treatment is unimportant.

Some group members may not be clear about some of the ideas introduced in this exercise. For example, not everyone will be familiar with the use of a hypothesis or with intention to treat. It is a good idea to have some examples prepared as this will help to clarify issues which, while they are widely talked about, are not always well understood.

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An introduction to statistical analysis

Some participants may be confident about statistics, so you may wish to offer them the option of moving straight onto the critical appraisal of an RCT exercise (page 50). However bear in mind that some people 'do not know what they do not know', so a better way may be to ask those who are familiar to help in introducing these concepts to the rest of the group. The 'pre-assessment' of group members may help you to decide which way to proceed.

You may find it useful to invite a statistician to help with this session.

Explain that an understanding of statistics is important because the likelihood of an observed outcome being due to chance is explored using statistical methods.

Show *Slide 5.5 – Questions to ask of an RCT*.

Discuss each point using the information below.

The role of chance

Single sets of observations

For participants to comprehend the role of chance they must understand that a single set of observations, even if selected in an unbiased way, may misrepresent the truth because of random variation. In fact a single observation is unlikely to correspond exactly to the true state of affairs in the population of all patients (there is no such thing as 'an average patient'). If the observations were repeated on many such samples, they may be found to vary. Thus we have to decide:

- did the outcome occur by chance?
- if not, what is the true value of the intervention or treatment?

Random variation

The divergence, when due to chance alone, of a sample observation from the true population value is called random variation. The purpose behind an RCT is to help investigators to estimate the probability of a result having occurred by chance. If this is unlikely, they will conclude that the specific intervention increased the likelihood of a particular outcome.

Coin-tossing to explore random variation

Time: approx 5 minutes

The point to be made from this exercise is that the same effects apply when assessing the effects of treatments. Chance can affect all the steps involved in clinical observations: sampling of patients, selection of treatment groups, and measurements made on the groups. This is where statistics can be used to estimate the probability of chance accounting for clinical variation.

This may be a good time to introduce the concept of probability, ie the probability of getting a head when tossing a coin once is 1 in 2, which can also be expressed as 0.5.

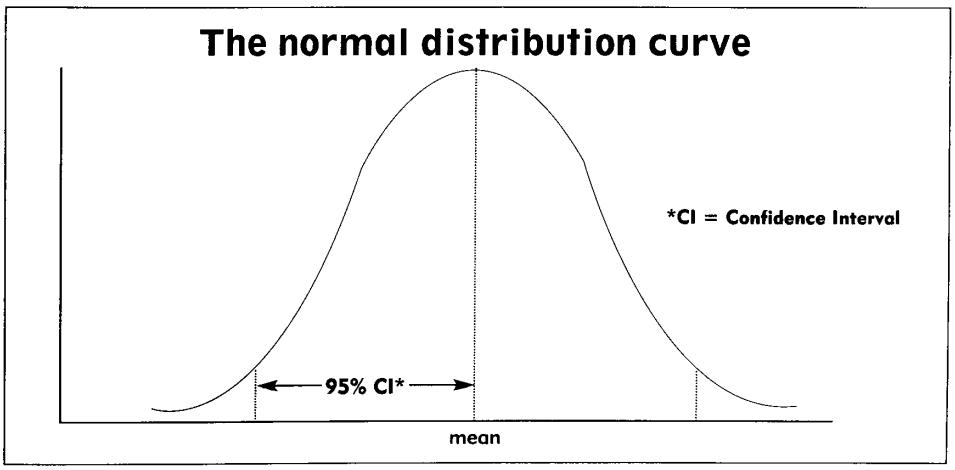
1. Ask one participant to flip a coin six times.
2. If the number of heads is not three, this demonstrates that there is random variation.
3. If the outcome is three heads, ask another participant to flip until someone flips more or less than three heads.

Of course there are times when the coin does come down three times as heads and three times as tails in which case the number of tosses can be increased.

Normal distribution

- Values are normally distributed when the majority of sample values cluster around the mean (average) with few cases falling at the extreme parameters of the measurement both above and below the mean.
- When plotted on a graph they form a symmetrical bell-shaped curve (see below). The shape of the curve is defined by the mean (reflecting its centre) and the standard deviation (reflecting the spread of observations).

You may wish to illustrate this on a flipchart.



Group work: coin tossing to generate normal distribution

Time: approx 20 minutes

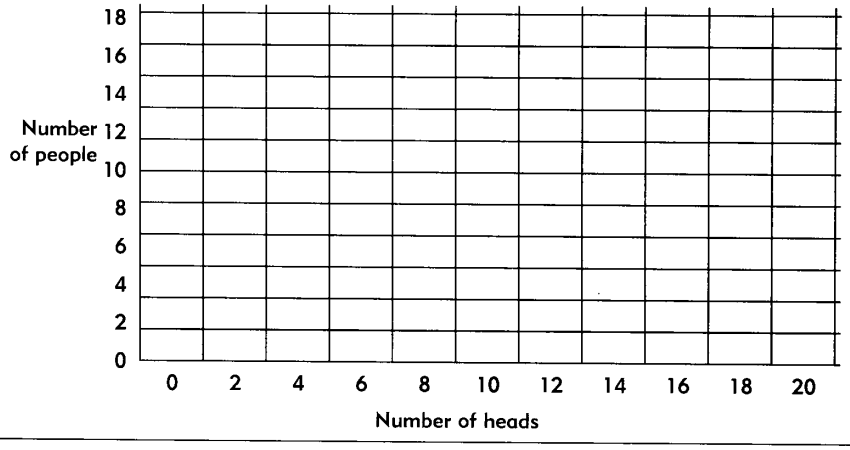
Divide the group into pairs.

Each pair should flip a coin 20 times and note how many heads they obtain.

Plot the results of each pair on a graph (see below) on a flipchart to demonstrate the spread.

Generate a short discussion as to whether participants feel the curve represents a normal distribution. If it doesn't ask why they think this is the case?

Plot the results on a graph to demonstrate the spread



Some group members may feel confident about their understanding of normal distribution curves and the above exercise may not be applicable. However it is well worth checking this out in advance. Unexpected results can also be used in this exercise as a convenient way of introducing the importance of sample size.

Confidence intervals

The discussion of the normal distribution introduced the idea of the spread which occurs around the mean, or average, which leads on to the notion of how precise the results are. For a given trial, this spread can be expressed as a confidence interval.

Confidence intervals (CIs) enable you to measure the degree of precision with which you can be sure that a particular outcome will occur.

The confidence value (typically 95%) tells you how sure you can be that the *range* includes the true value.

The larger the *sample size*, the smaller the CI range becomes.

Understanding confidence intervals

Time: approx 10 minutes

You will need an opaque bag containing two types of sweet of the same size and shape. Put in an appropriate number of each type of sweet for the group size (around two to three sweets for each group member).

Question: How may sweets of each type are there in the bag? (Null hypothesis – there is no difference in the number of sweets of each type).

Pass the bag round the group, asking each person to take one out. Record the number of sweets of each type drawn.

Repeat this until all the sweets are gone. Generate a table of the results through progressive rounds (see example below).

Understanding confidence intervals

Total number of sweets drawn from the bag	Number of type 1 sweets	Number of type 2 sweets	Range for number of type 1 sweets (confidence interval)
0	?	?	0–Total
1st experiment	N	M	(O+N)–(T–M)
2nd experiment	P	Q	(O+N+P)–(T–M–Q)
Further experiments			Number of type 1 sweets

Points to draw out of this exercise are that:

- **increasing the sample size (which occurs with each round of 'experiments') decreases the confidence interval**
- **and hence increases the precision with which the number of type 1 sweets can be estimated.**

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Are these results significant?

Measure strength of evidence

Significance tests measure the extent the observed data supports a given proposition (the null hypothesis).

Chance result

To do this, the tests calculate the probability of the result having occurred by chance, assuming the null hypothesis to be true.

Significance levels

It has become generally accepted that a level of $p<0.05$ should be considered as a significant result, ie you accept a 1 in 20 risk that the result has arisen by chance alone.

A level of $p<0.001$ is considered highly significant. In this case, there is a 1 in 1000 risk that the result has arisen by chance alone.

To summarise, significance tests:

- measure the strength of evidence which the data supplies for or against a proposition
- if the probability is small then the data is unlikely to have arisen by chance
- by convention:
  - significant result $p<0.05$ (1 in 20 chance)
  - highly significant $p<0.001$ (1 in 1000 chance).

Common statistical tests

Statistical tests are used to help us determine whether there is a difference between two (or more) samples of a population, ie if two groups studied in a trial have different outcomes, is this as a result of the different treatments, and not due to chance? If the data we are dealing with follows a normal distribution then the type of statistical tests that are used for comparison of groups are called parametric tests. Examples of common tests that are frequently used to analyse research studies are given below. Participants may find it helpful if you note these on a flipchart as each one is explained.

1. If data is continuous, ie a range of values will be expected, then to tell if, for example, Treatment A is better than Treatment B, a '*T*' test (or *Students T*) is often used. This test is based on looking for differences in the means and standard deviations of groups.

2. If data is categorical ie Yes or No, then to tell if, for example, more people had loss of appetite when taking drug A compared to drug B, then a *chi squared* test or *Fishers' exact test* is most commonly used. These are based on a 2 x 2 table (see ***Chapter 8 Diagnostic tests***) and look for differences in the number of observed outcomes versus the expected number.
3. To look for differences over time, eg gastric pH after two hours of fasting compared to after eight hours of fasting, then a common test to use to say whether the changes over time are significant is the *paired t* test.

All the tests outlined above are based on data that has a normal distribution. If however there is no evidence that data follows a normal distribution, and is unlikely to do so, eg quality of life data, then different tests should be used which are called *non parametric*. Below are the names of some common *non parametric* tests, the numbers refer to the above scenarios (1–3), but are used when data does not follow a normal distribution:

1. Mann Whitney U
2. Fishers' exact
3. Wilcoxon matched pairs signed rank test.

You may find it helpful to remind participants of the normal distribution curve. Examples can be given of where normal data may not occur, eg quality of life measures.

It is important for participants to be able to establish whether the group being studied in an RCT follows a normal distribution, in order to establish what sort of statistical testing should be applied.

It is usually only appropriate to familiarise participants with names of statistical tests that they are likely to see in published articles, eg Mann Whitney U. If the group is more advanced then longer can be spent on the use of these tests.

Critical appraisal of an RCT paper

Time: 30 minutes

1. Divide participants into small groups.
2. Provide them with copies of **Handout 5.1 Checklist for appraising a Randomised Controlled Trial.**
3. Ask them to critically appraise your choice of an RCT paper (see below for suggestions).
4. Bring the participants back together to feedback answers, and generate discussion.

If time is short you could ask each group to answer different questions from the checklist.

This exercise can be done away from the group setting in which case it can be used as a discussion point the next time the group meets.

Recommended papers:

1. Imperial Cancer Research Fund General Practice Research Group (1993) Effectiveness of a nicotine patch in helping people stop smoking: results of a randomised trial in general practice. *British Medical Journal* **306** 1304–8.
2. Kerr, S.M., Jowett, S.A. & Smith, L.N. (1996) Preventing sleep problems in infants: a randomised controlled trial. *Journal of Advanced Nursing* **24** 938–942.

Further reading

Altman, D. (1996) Better reporting of randomised controlled trials: the CONSORT statement. *British Medical Journal* **313** 570–571.

Behi, R. (1995) The nature of scientific knowledge: fact or theory? *British Journal of Nursing* **4** (4) 221–224.

Chalmers, I. (1986) Minimising harm and maximising benefit during innovation in health care: controlled or uncontrolled experimentation? *Birth* **13** (3)155–164.

Corbett, F., Oldham, J. & Lilford, R. (1996) Offering patients entry in clinical trials: preliminary study of the views of prospective participants. *Journal of Medical Ethics* **22** 227–231.

Crombie, I. (1997) *Pocket Guide to Critical Appraisal*. London: British Medical Journal Publishing Group.

Greenhalgh, T. (1997) *How to Read a Paper. The Basics of Evidence-based Medicine*. London. British Medical Journal Publishing Group. (See chapter 3: Health Research Methodologies and Appraising Quantitative Studies, and chapter 11: Appraising Qualitative Research).

Mulhall, A. (1994) The experimental approach and randomised controlled trials. In: M. Hardey & A. Mulhall (Eds) (1994) *Nursing Research, Theory and Practice*. London: Chapman & Hall.

Sackett, D. & Wennberg, J. E. (1998) Choosing the best research design for each question. *British Medical Journal* **315** 20–27.

Sajiwandam, J. (1996) Ensuring the trustworthiness of quantitative research through critique. *NT Research* **1** (2) 135–141.

Sibbald, B. & Roland, M. (1998) Why are randomised controlled trials important? *British Medical Journal* **316** 201.

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Chapter 6

Systematic reviews

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Introduction

Systematic reviews produce a summary answer to a question by bringing together the results of studies dealing with the same subject. The answer is robust if the review is conducted according to a rigorous methodology. Systematic reviews therefore differ from the previously more common type of review in which an expert sets down his or her opinion, citing a number of references in support of this view.

Systematic reviews, in contrast, aim to consider all the evidence relating to a particular problem. They can help resolve disagreement between studies and can increase the precision with which an effect is measured. A well-conducted systematic review contains very robust evidence.

Aims

- to understand systematic review methodology
- to feel confident in reading and appraising systematic reviews.

Objectives

For participants to:

- think about different ways of presenting data
- understand relative risk, attributable risk and numbers needed to treat
- consider what makes a good systematic review
- know what odds ratios and confidence intervals are and to be able to interpret a 'blobbogram'
- calculate numbers needed to treat.

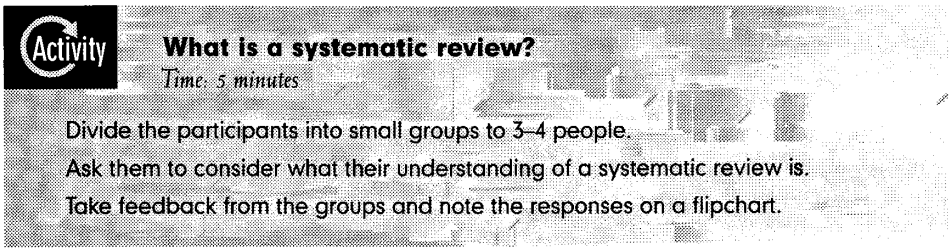
Timing

Approximately 2 hours.

Materials

- *Slides 6.1, 6.2, 6.3, 6.4*
- *Handouts 6.1, 6.2* (enough copies for all participants)
- Flipchart
- Your choice of paper to be critically appraised – copies for all participants (see Activity on page 59.)

What is a systematic review?



Systematic reviews: discussion

To reinforce the general discussion about the attributes of systematic reviews you may find it useful to refer to *Slide 6.1*. The main points to elaborate are:

- **distinguish systematic review (bringing together all studies addressing a similar question) from meta-analysis (statistical analysis to produce a summary result from all trial results), which may or may not be part of a systematic review**
- **systematic reviews require tight protocols that describe methodology. For example, information is required about how articles were identified, the inclusion/exclusion criteria, how the quality of studies was ascertained and the form of analysis.**

The following quotations help distinguish the difference between systematic reviews and meta-analysis.

Systematic review

'a systematic approach to preparing a review to minimise bias and random error.'

Meta-analysis

'the quantitative synthesis of primary data to yield an overall summary statistic.'
(Chalmers & Altman, 1995)

Show ***Slide 6.2 – Meta-analysis in systematic reviews.***

This shows the main characteristics of a meta-analysis.

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Forest plot

Results from a meta-analysis are presented graphically. It is important that participants are able to interpret a 'blobbogram' (or Forest plot), which is the name given to the graphical representation.

It is useful to give an example of a blobbogram. Show *Slide 6.3* or alternatively, draw the parts of the blobbogram on a flipchart as you describe them.

Forest plot: describing the plot

Describe the component parts of the graph, the symbols and the terms used:

- ■ Individual trial result, which are usually presented as an odds ratio. The size of the box often indicates the number of subjects in the trial
- — 95% confidence interval around the point estimate
- ◇ Pooled odds ratio and confidence interval of a group of trials
- ◆ Pooled result of all trials.

Odds ratio

Odds ratio = 1 : no difference between treatment & control groups

Odds ratio < 1 : treatment more effective than control

- If the confidence interval crosses the line of odds ratio (the central vertical line), then the result is not significant.
- If the pooled results of all trials is to the right of the central line the result shows that the experimental therapy is significantly better; if the odds ratio lies to the left the experimental treatment is significantly worse, and if it touches the central line, there is no significant difference between the treatments.

Odds ratio

If the participants are not familiar with odds and odds ratios, ***Slide 6.4*** gives a definition for each.

When describing odds, betting odds for horse racing is an example that many people can grasp. The odds look at dichotomous outcomes – a horse that is given the odds 5 to 2 is expected to win 5 races out of 7 run, with an odds ratio of 5 ÷ 2 = 2.5 to 1.

Having described odds, run through a calculation of the odds ratio on a flipchart.

The results of randomised controlled trials combined or meta-analysed in systematic reviews, are often presented as odds ratios. These are calculated from 2 x 2 tables as follows:

Dichotomous outcome example

Outcome	Group 1	Group 2
Win	a	b
Lose	c	d

Odds (chance) of winning in group 1 = a ÷ c

Odds (chance) of winning in group 2 = b ÷ d

Odds ratio = odds of winning group 1 divided by odds of winning group 2

$$= \frac{(a \div c)}{(b \div d)}$$

$$= ad \div bc$$

When the odds ratio is 1, there is no difference in outcome between the two groups. Odds ratios of less than 1 favour the first group. Conventionally group one is the treatment group and group two the control group.

Different ways of presenting treatment data have now been covered in the critical appraisal of randomised controlled trials session and this workshop. The following activity will help ensure that participants have begun to understand the different statistical concepts.

Activity

Presenting results of clinical trials

Time: 30 minutes

(This exercise is based on: Fahey, T., Griffiths, S. & Peters, T.J. (1995) Evidence-based purchasing: understanding results of clinical trials and systematic reviews. *British Medical Journal* 311 *1056–60.)*

Ask participants to work as individuals for steps 1 to 3.

1. Distribute **Handout 6.1**, which sets out a scenario about implementing a breast screening programme and describes the results of four different programmes relating to this.
3. Ask each individual to rate the four programmes according to the rating scale in the handout.
4. Share the rankings.
5. Discuss how convincing the evidence is.

The programmes represent four different ways of presenting the same data. Not everyone will spot this.

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Programme A – Relative risk reduction

Compares the risk in those exposed to the intervention with those not exposed (controls), but it tells us nothing about the magnitude of the incidence (absolute risk).

Programme B – Absolute risk reduction

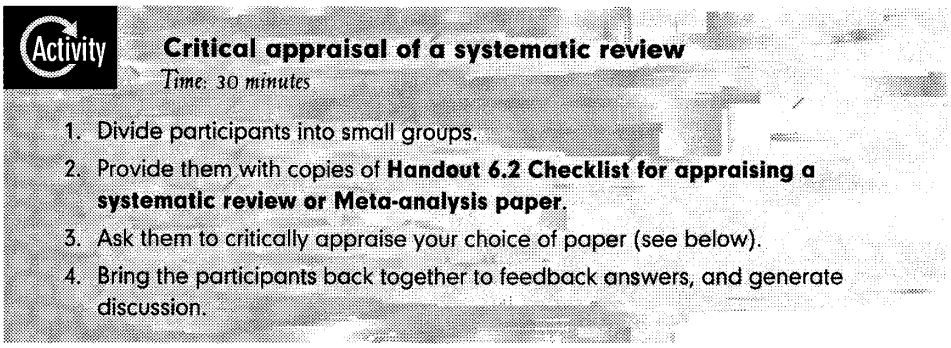
This offers, perhaps, a more useful measure of risk as absolute risk. This looks at 'how much does a risk factor contribute to the overall rates of disease in groups of people, rather than in individuals'. This information is useful for deciding which risk factors are particularly important and which are trivial to the overall health of a community. It may be the case that a weak relative risk factor that is prevalent could account for more of the overall incidence of a disease in a community than a higher relative risk reduction in a disease that is rarely present.

Programme C – Proportion of event-free patients

Another way of looking at risk in a population is to look at the proportion of event-free patients. This compares the percentage of patients in a community who remain without the disease in the group exposed to the intervention compared to those who are not.

Programme D – Number needed to treat (NNT)

The evidence based practice movement is encouraging clinicians to express risk in terms of the number of patients you need to treat to prevent one adverse outcome as this is perhaps the simplest concept to understand.



If time is short you could ask each group to answer different questions from the checklist or you may wish each group to look at a different section of the appraisal and then take group feedback.

This exercise can be done away from the group setting in which case it can be used as a discussion point the next time the group meets.

Suitable papers

Stroke Unit Trialists' Collaboration (1997) Collaborative systematic review of the randomised trials of organised inpatient (stroke unit) care after stroke. *British Medical Journal* **314** 1151–9.

Moore, R. A., Tramer, M. R., Carroll, D., Wiffen, P. J. & McQuay, H. J. (1998) Quantitative systematic review of topically applied non-steroidal anti-inflammatory drugs. *British Medical Journal* **316** 333–8.

Fletcher, A., Cullum, N. & Sheldon, T. (1997) A systematic review of compression treatment for venous leg ulcers. *British Medical Journal* **315** 576–80.

Calculating relative risk, attributable risk reduction and Numbers Needed to Treat (NNTs)

It can be useful to finish this session by getting participants to work through some figures from the appraisal paper to help them understand where these different numbers are derived from. It is advisable to have worked through the figures beforehand to draw up an answers sheet.

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Draw up a 2 x 2 table as shown below summarising the results from the study.

Calculating relative risk, attributable risk and NNT

	New treatment	Control	Total
Outcome YES	a	b	a+b
Outcome NO	c	d	c+d
Total	a+c	b+d	a+b+c+d

You may wish to work through the example algebraically at first before inserting outcome data from the study. Participants can be invited to calculate NNTs for subsequent outcomes.

Risk of outcome with treatment group $a \div (a+c)$

Risk of outcome in control group $b \div (b+d)$

Relative risk

= risk of outcome in treatment group ÷ risk of outcome in control group

$$= \frac{a \div (a+c)}{b \div (b+d)}$$

$= a(b+d) \div b(a+c)$

$= (ab+ad) \div (ba+bc)$

Relative risk approximates to odds ratio ($= ad \div bc$) when outcome is uncommon.

Absolute or attributable risk reduction (ARR)

= risk of outcome in control group – risk of outcome in treatment group

$= b \div (b+d) - a \div (a+c)$

Number Needed to Treat

$NNT = 1 \div ARR$

References

Chalmers, I.& Altman, D. G. (Eds) (1995) *Systematic Reviews*. London: British Medical Journal Publishing Group.

Further reading

Chalmers, I. & Altman, D. G. (Eds) (1995) *Systematic Reviews*. London: British Medical Journal Publishing Group.

Davey Smith., G. & Eggar, M. (1998) Meta-analysis. Unresolved issues and future developments. *British Medical Journal* **316** 221–225.

Droogan, J. & Cullum, N. (1998) Systematic reviews in nursing. *International Journal of Nursing Studies* **35** 12–13.

Greener, J. & Grimshaw, J. (1997) Using meta-analysis to summarise evidence within systematic reviews. *Nurse Researcher* **4** (1) 27–38.

Greenhalgh, T. (1997) Papers that summarise other papers. *British Medical Journal* **315** 672–675.

Naylor, C. D. (1997) Meta-analysis and the meta-epidemiology of clinical research. *British Medical Journal* **315** 617–619.

Oxman, A. D., Cook D. J & Guyatt, G. H. (1994) Users' guide to the medical literature VI. How to use an overview. *JAMA* **272** (17) 1367–1371.

Skolbekken, J. A. (1998) Communicating the risk reduction achieved by cholesterol reducing drugs. *British Medical Journal* **316** 1956–1958.

University of York NHS Centre for Reviews and Dissemination (1996) *Undertaking systematic reviews of research on effectiveness: CRD guidelines for those carrying out or commissioning reviews*. (CRD report 4.) York: University of York.

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Chapter 7

Qualitative research

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Introduction

Healthcare is an art as well as a science and there are many questions which do not lend themselves to experimental designs. Understanding the rationale of why people behave as they do is just as important as quantitative information for the development and delivery of healthcare according to its broadest definition.

Qualitative research methods have been of central importance to social scientists. They are increasingly being applied in healthcare to provide a deeper understanding of clinical and organisational issues.

Aim

- to appreciate the contribution qualitative research can make to answering questions related to healthcare.

Objectives

For participants to:

- understand the components of a good qualitative study
- identify questions which are more appropriately answered through the use of qualitative methods
- feel confident in appraising a qualitative research paper using a checklist.

Timing

Approximately 1 hour.

Materials

- *Slides 7.1, 7.2, 7.3, 7.4, 7.5*
- *Handouts 7.1, 7.2, 7.3, 7.4, 7.5* (enough copies for all participants)
- Flipchart
- Your choice of paper from ***Handout 7.1*** (see Activity on page 70).

The starting point for this seminar is a clinical scenario which is thematically linked to a research paper to be appraised. You may wish to choose a scenario from those on *Handout 7.1* and use it throughout the workshop OR, alternatively, select your own scenario.

In a series of steps, participants are invited to build up the methodology for a qualitative research project to address issues raised by the scenario. Prompts and slides have been included to help to introduce the terminology and to fill in gaps in participants' knowledge about qualitative methods.

If the audience is sceptical about the justification for qualitative methods it is important to demonstrate its strengths in this workshop.

Critical appraisal of a qualitative research paper

Setting the scenario

Time: 5 minutes

Having decided which of the three case scenarios on **Handout 7.1** (or an alternate scenario) you would like to work with, ask participants what questions they might want to ask if they were faced with this scenario?

Once you have run through the scenario and identified a series of questions, ask the group what would be the best research approach they would take to find answers to those questions.

You may find it helpful to have generated a list of issues for your chosen scenario before the session in order to ensure that a range of different approaches may be employed to answer the questions. For example, in the scenario about Mr Evans' smoking you may wish to know:

- how knowledgeable is Mr Evans (and others) about the effect of smoking? – questionnaire/survey
- why does he see the doctor's behaviour as 'interfering'? – unstructured interview, qualitative approach
- what factors in Mr Evans' life may influence his reaction to the advice to stop smoking? – observation/questioning about lifestyle
- how could the patient/GP interaction have been modified to gain greater understanding? – observation/video.

None of these questions could be dealt with in a controlled trial. Nevertheless considerable insight into the issues raised can be gained by other means.

For example, returning to the questions highlighted above, action research, on a cyclical basis, may be used to develop the doctor/patient relationship while phenomenology may help gain insight into how Mr Evans perceives the control he has over his own life.

Qualitative research: a definition

Having elicited from the participants that they may want to use qualitative methods in some instances, it is useful to give a definition of what qualitative research is about – show *Slide 7.1*. The emphasis is that qualitative research studies natural settings, and looks at what things mean to patients, and at patients' experiences and their views. In a simplified definition, qualitative research allows us to ask *why*, rather than *what*.

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Why do qualitative research?

To explore the purpose of qualitative research further a second question can be posed: 'Why do qualitative research?' – show ***Slide 7.2***. It is well accepted that qualitative research can be used to generate hypotheses for later investigation by quantitative methods, but it has a lot more to offer.

For example, it can confirm the meaning and context for quantitative work and can answer new and different questions from those answered by quantitative methodologies. Qualitative methods can look at the complexity of healthcare. They can also identify hidden issues which may influence healthcare outcomes and suggest ways of tackling problems.

Qualitative research methods

As with quantitative research it is important to understand the different methods that can be used for qualitative research, since they study different aspects of care. The various methods are listed in ***Handout 7.2***.

The question being asked should dictate which method would be best in that instance.

To ensure that participants have understood the different methodologies, you may wish to reflect back to the original chosen scenario and ask which broad methodological approach would match each of the questions posed. You may also wish to reconsider the questions generated at the start of this session as greater insight is gained into the way in which qualitative research methods can be used.

Sampling in qualitative research

As qualitative research is concerned with the intensive analysis of a small number of cases, statistical representativeness is of less concern than the quality of the information elicited from the sample. The researchers must ensure that they are explicit about which relevant groups or categories they systematically included in their samples. ***Handout 7.3*** lists different types of sampling methods.

Data Collection

Now that methods and sampling have been introduced we recommend that you move on to consider data collection.

Data collection
Time: 10 minutes

1. Ask the participants to return to their original ideas about gathering data related to the chosen scenario (**Handout 7.1**) and, in the light of discussion, to think again about how they might go about collecting the data.
2. Then distribute **Handout 7.4** and compare their answers to those it contains. It gives the correct terminology for qualitative approaches to data collection.

Bias in qualitative research

The next issue to be introduced is that of bias. In quantitative work objectivity is sought throughout the process. In qualitative work subjective meanings and interpretations are explored. However it is equally important to be aware of the risk of bias and to find ways of minimising the risk of it interfering with interpretation.

Managing bias
Time: 5 minutes

This activity is concerned with helping the participants to explore how bias is managed in qualitative research.

1. It may be helpful to prompt the group with a question such as 'What about the role of the researcher – might there be any bias?' in order to encourage them to think about sources of bias in qualitative research. Note their responses on a flipchart.
2. Participants' views can then be compared with the following list, which illustrates some of the ways that the characteristics of the researcher may affect the study they are carrying out, in terms of both access to the study situation and the responses elicited from study participants.

   'A researcher's access to, and reception in a fieldwork setting will be affected by social and personal characteristics... (which) include:

   - age
   - marital status
   - ethnic origin
   - accent
   - physical appearance
   - sex
   - sexual preferences
   - social class
   - past biography
   - dress'

   (Scottish Consensus Statement on Qualitative Research in Primary Health Care, 1995)

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Analysing the results

Time: 5 minutes

This exercise is used to help participants gain insight into ways in which qualitative research can be analysed.

1. Ask participants if they have any prior knowledge of how they might analyse the results of qualitative research, in order to encourage them to think about methods of analysis in qualitative research.
2. Then compare their list to the one shown on **Slide 7.3**.

In qualitative research, analysis is integral throughout the research period, from generating and developing an idea to the final writing stage. It is not a distinct phase, undertaken only after all the data is collected.

It begins with the planning of a good system of recording, retrieving and coding data. This is the first link between data and theory, generating categories and later concepts.

Computer software packages are now available to assist with the organisation and analysis of copious amounts of data but the considerable time taken to analyse qualitative research studies must not be underestimated.

Validity

Once analysis has been completed it is important to consider the validity of the data. There are two main ways of checking for validity, namely triangulation and respondent validation.

1. Triangulation

In triangulation, comparisons are made by looking at the same problem in different ways, using alternative sources of information or interpretation. Any marked differences can be highlighted, investigated and explained. Data items may be corroborated by using:

- different sources of data about the same phenomenon
- different methods of collecting the same data
- multiple analysts who compare interpretation of the same data.

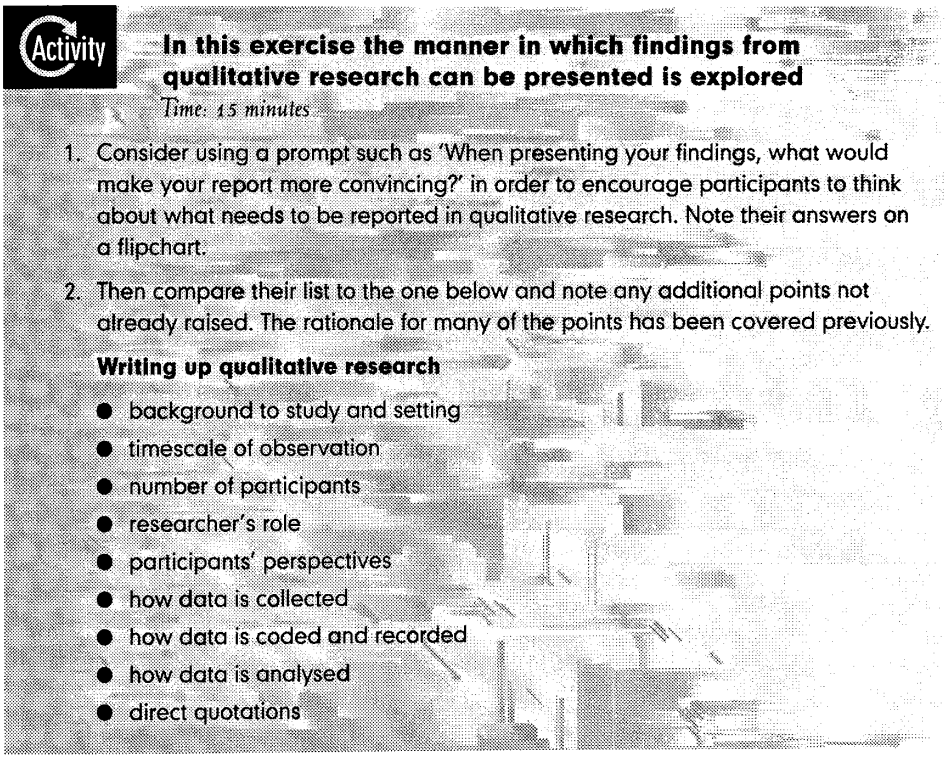
2. Respondent validation

The researcher can test and retest his or her interpretations in the field. If respondents agree with the data or interpretation that is fed back to them, this adds to the credi-

bility of the research. Using the same process with subsequent respondents can enlarge the data source and confirm or challenge the ideas derived from the initial study group.

Writing up qualitative research

The way in which qualitative research is written up differs from the clear linear process of quantitative reports. There are, however, important points which need to be addressed in order to ensure that the work can be interpreted with integrity.



In this exercise the manner in which findings from qualitative research can be presented is explored

Time: 15 minutes

1. Consider using a prompt such as 'When presenting your findings, what would make your report more convincing?' in order to encourage participants to think about what needs to be reported in qualitative research. Note their answers on a flipchart.
2. Then compare their list to the one below and note any additional points not already raised. The rationale for many of the points has been covered previously.

Writing up qualitative research

- background to study and setting
- timescale of observation
- number of participants
- researcher's role
- participants' perspectives
- how data is collected
- how data is coded and recorded
- how data is analysed
- direct quotations

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Transferability

Time: 5 minutes

In order to get participants thinking about the transferability of a piece of qualitative research it is helpful to frame a question such as 'What criteria do you have for deciding whether or not a study is transferable to your own clinical setting?' If necessary, use the prompts 'Were the subjects in the study similar in important aspects to your own patients?' and 'Is the context similar to your own practice?' This should prompt a discussion about the generalisability of the study.

Critical appraisal exercise

Time: 20 minutes

Use the initial paper from which your scenario was taken for this exercise.

1. Ask participants to move into groups of 2 to 4.
2. Ask them to carry out a critical appraisal, using **Handout 7.5 Checklist for appraising a qualitative paper**.
3. Take feedback with the whole group.

If time is short, different groups can carry out different parts of the appraisal. Alternatively the group may prefer to undertake this activity away from the group session, bringing feedback next time they meet.

Summary

It is helpful to recap on the strengths of qualitative research and how it differs from, but complements, the quantitative methodologies. The issues highlighted on ***Slide 7.4*** may help in this discussion.

The role in healthcare of non-quantitative methods

An optional final slide for the qualitative research session is ***Slide 7.5***, reinforcing that there is a role in healthcare for non-quantitative methods.

Further reading

Boulton, M. & Fitzpartick, R. (1997) Evaluating qualitative research. *Evidence-based Health Policy and Management*. December 83–85.

Burgess, R. G. (1995) In the Field. *Contemporary Social Research* **8**. M. Bulmer (Ed).

Denzin, N. K. & Lincoln, Y. S. (1994) *Handbook of Qualitative Research*. London: Sage.

Dowell J., Huby, G. & Smith, C. (1995) *Scottish Consensus Statement on Qualitative Research in Primary Health Care*. Dundee: Tayside Centre for General Practice, University of Dundee.

Forchuck, C. & Roberts, J. (1993) How to critique qualitative research articles. *Canadian Journal of Nursing Research* **25** (4) 47–56.

Greenhalgh, T. (1997) *How to Read a Paper. The Basics of Evidence-based Practice*. London: British Medical Journal Publishing Group.

Hill Bailey, P. (1997) Finding your way around qualitative methods in nursing research. *Journal of Advanced Nursing* **25** 18–22.

Jones, R. (1995) Why do qualitative research? *British Medical Journal* **331** (6996).

May, N. & Pope, C. (Eds) (1996) *Qualitative Research in Health Care*. London: British Medical Journal Publishing Group.

Mays, N. & Pope, C. (1996) *Qualitative Research in Health Care*. London: British Medical Journal Publishing Group.

Needleman, C. & Needleman, M. L. (1996) Qualitative methods for intervention research. *American Journal of Industrial Medicine* **4** 329–337 April 29.

Pope, C. & Mays, N. (1995) Reading the parts other methods cannot reach: an introduction to qualitative methods in health services research. *British Medical Journal* **311** (6996).

Robinson, K. (1994) Research methods – an overview. *Surgical Nurse* **7** (2) 9–11.

Sackett, D. & Wennberg, J. E. (1998) Choosing the best research design for each question. *British Medical Journal* **311** (6996).

Streubert, H. J. & Carpenter, D. R. (1995) *Qualitative Research in Nursing: Advancing the Humanistic Imperative*. Philadelphia: Lippincott.

Winter, J. C. (1990) Relationship between sources of knowledge and use of research findings. *The Journal of Continuing Education in Nursing* **21** (3) 138–140.

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Chapter 8

Diagnostic tests

Introduction

Healthcare is increasing in complexity. Technological revolution in the biomedical sciences is producing more and more diagnostic tests. But do they help the patient and the clinician? The purpose of a diagnostic test is to increase the accuracy in making a diagnosis by confidently separating those with the condition from those without it. The ideal test is accurate every time it is applied. But do all tests meet that stringent criterion?

It may well be harmful to falsely give the all-clear to somebody with a disorder. There can also be anxiety and morbidity associated with erroneously diagnosing a well individual as being ill, and a test may not add any useful additional information to the clinical history and examination. All these properties of a diagnostic test will be explored in this section.

Aim

- to impart confidence in understanding whether or not a diagnostic test is useful.

Objectives

For participants to:

- become familiar with a 2 x 2 table and the concepts of false positive and false negative test results
- learn how to calculate sensitivity, specificity, positive predictive values, negative predictive values and likelihood ratios and to understand the implications of changes in these properties on the usefulness of diagnostic tests

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- understand the concepts of pre-test probability and post-test probability – does performing the test alter patient management?
- be able to critically appraise a diagnostic test paper.

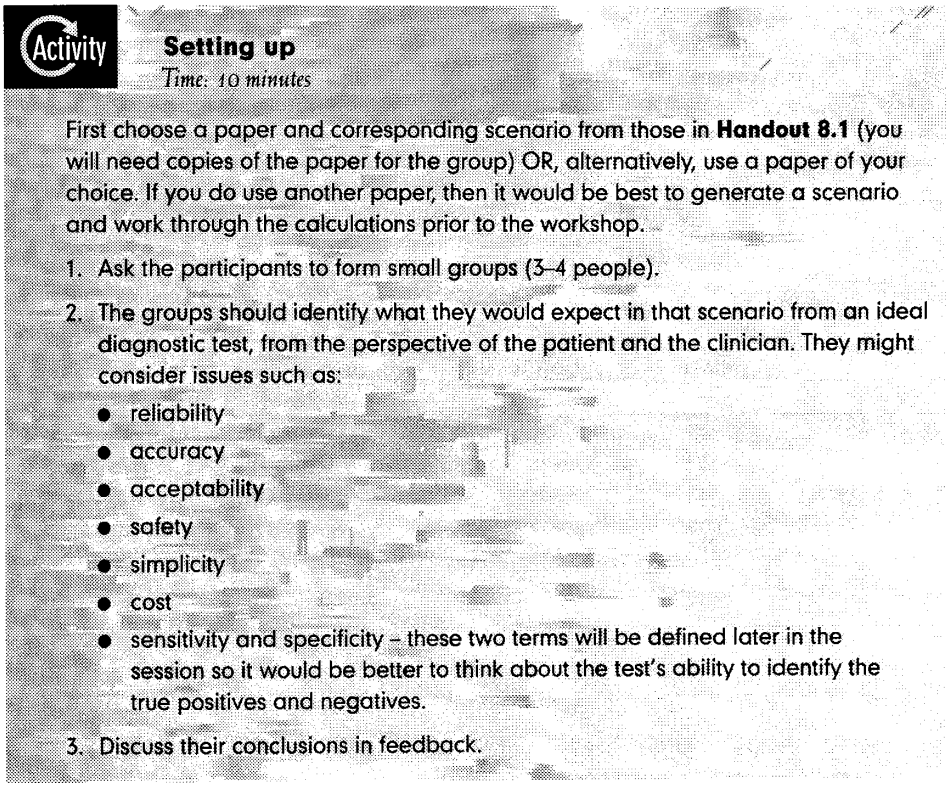
Timing

Approximately 1 1/2 hours.

Materials

- *Slides 8.1, 8.2, 8.3, 8.4, 8.5, 8.6*
- *Handouts 8.1, 8.2, 8.3* (enough copies for all participants)
- Flipchart
- Your choice of paper from ***Handout 8.1*** (see Activity on page 75).

How useful are diagnostic tests?



Activity

Setting up

Time: 10 minutes

First choose a paper and corresponding scenario from those in **Handout 8.1** (you will need copies of the paper for the group) OR, alternatively, use a paper of your choice. If you do use another paper, then it would be best to generate a scenario and work through the calculations prior to the workshop.

1. Ask the participants to form small groups (3–4 people).
2. The groups should identify what they would expect in that scenario from an ideal diagnostic test, from the perspective of the patient and the clinician. They might consider issues such as:
   - reliability
   - accuracy
   - acceptability
   - safety
   - simplicity
   - cost
   - sensitivity and specificity – these two terms will be defined later in the session so it would be better to think about the test's ability to identify the true positives and negatives.
3. Discuss their conclusions in feedback.

Usefulness of a diagnostic test

To assess the usefulness of a diagnostic test it is important to be able to draw up a 2 x 2 table, the properties of which are shown in *Slide 8.1*.

When explaining the meaning of this table it is best to start with the true situation, that is *condition present* and *condition absent* before thinking about false positives and false negatives.

Tip

Seek examples from the group of tests they know that have false positive and/or false negative results and generate a discussion as to whether or not this matters. This leads to the conclusion that ways are needed to assess diagnostic tests to ascertain which ones are useful and in what situations.

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Critical appraisal of the paper

Time: 15 minutes

1. Participants should re-form into groups.
2. Distribute **Handout 8.2** and the chosen paper for appraisal and ask them to apply the questions to the chosen paper. These questions cover the validity of the study.
3. Discuss their conclusions in a plenary session.

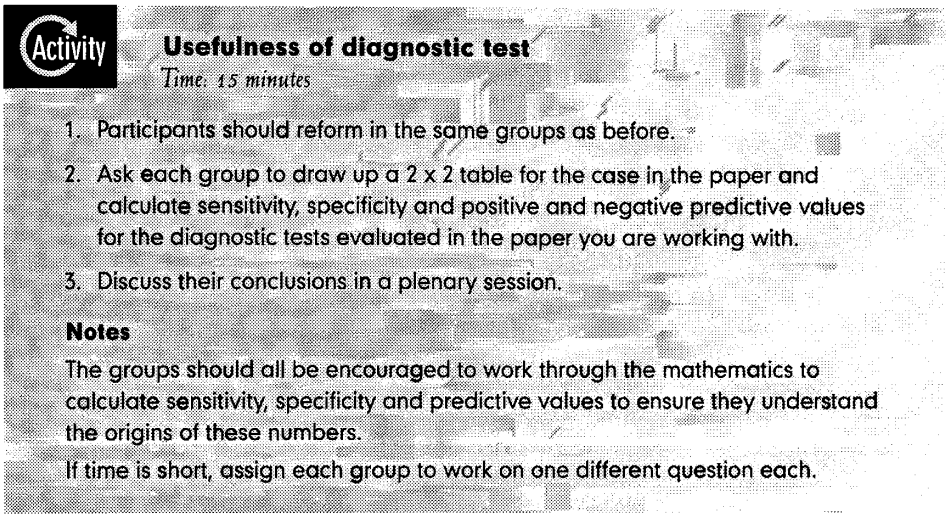
If the audience is unfamiliar with the term *gold standard* it may be worth spending a couple of minutes explaining it in the context of diagnostic tests. A *gold standard* treatment is a well recognised 'best test' for diagnosing a condition, eg for diabetes the World Health Organisation has defined it as 'a blood glucose concentration above 8 mmol/L in the fasting state or above 11 mmol/L two hours after a 100g oral glucose load'. Therefore the gold standard tests are fasting bloods or glucose tolerance tests.

Properties of an ideal diagnostic test

Discuss the properties of an ideal diagnostic test, ie:

1. It correctly identifies as positive those people who truly have the condition.
   Sensitivity = a ÷ (a + c)
2. It correctly identifies as negative those people who truly do not have the condition.
   Specificity = d ÷ (b + d)
3. Those testing positive who do have the condition
   Positive predictive value = a ÷ (a + b)
4. Those testing negative who do not have the condition
   Negative predictive value = d ÷ (c + d)

These are illustrated in *Slide 8.2*.



Activity **Usefulness of diagnostic test**

Time: 15 minutes

1. Participants should reform in the same groups as before.
2. Ask each group to draw up a 2 x 2 table for the case in the paper and calculate sensitivity, specificity and positive and negative predictive values for the diagnostic tests evaluated in the paper you are working with.
3. Discuss their conclusions in a plenary session.

Notes

The groups should all be encouraged to work through the mathematics to calculate sensitivity, specificity and predictive values to ensure they understand the origins of these numbers.

If time is short, assign each group to work on one different question each.

Tip **Keep referring back to the scenario and the 2 x 2 table on *Slide 8.2*, to ensure participants understand both the definitions, and how to calculate, sensitivity, specificity and predictive values.**

Disease prevalence

Introduce the concept of disease prevalence:

- disease prevalence = pre-test probability of disease
- the disease prevalence affects the usefulness of doing a test

Worked examples on 2 x 2 tables

Work through the following examples on a flipchart, building up each 2 x 2 table (see **Examples 1**, **2** and **3**) to illustrate the point that, for given sensitivity and specificity of a particular test, the usefulness of that test falls as the disease prevalence falls.

The examples take a test that is 80% sensitive and 70% specific, applied to a population of 500. The effect is shown in *Slide 8.3*.

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For the calculations:

- **start with cell (i); the sensitivity of the test will give the true positives in the population who test positive**
- **next calculate cell (ii); here apply the specificity to the population to find the number of true negatives who test negative**
- **cell (iii) indicates the false positives – subtract (ii) from the total without the condition**
- **cell (iv) are the false negatives – subtract (i) from the total with the condition.**

EXAMPLE 1 In populations where the condition is 50% prevalent

ie in a population of 500, 250 will have the condition, and for 250 the condition will be absent.

	Condition present	Condition absent	Total
Test positive	0.8 × 250 = 200 (i)	75 (iii)	275
Test negative	50 (iv)	0.7 × 250 = 175 (ii)	225
Total	250	250	500

Positive predictive value = 200 ÷ 275 = 73%

Now change the prevalence of the condition and see how this affects the positive predictive value of the test. Work through Examples 2 and 3 to see that the performance of the test is less useful as the disease prevalence falls.

EXAMPLE 2 In populations where the condition is 10% prevalent

ie in a population of 500, 50 will have the condition, and for 450 the condition will be absent.

	Condition present	Condition absent	Total
Test positive	0.8 × 50 = 40	135	175
Test negative	10	0.7 × 450 = 315	325
Total	50	450	500

Positive predictive value = 40 ÷ 175 = 23%

EXAMPLE 3 In populations where the condition is 1% prevalent

ie in a population of 500, 5 will have the condition, and for 495 the condition will be absent.

	Condition present	Condition absent	Total
Test positive	0.8 x 5 = 4	148	152
Test negative	1	0.7 x 495 = 347	348
Total	5	495	500

Positive predictive value = 4 ÷ 152 = 3%

Likelihood ratio

The next step is to consider the likelihood ratio defined in ***Slide 8.4***. The likelihood ratio is a property of a diagnostic test that links its sensitivity and its specificity.

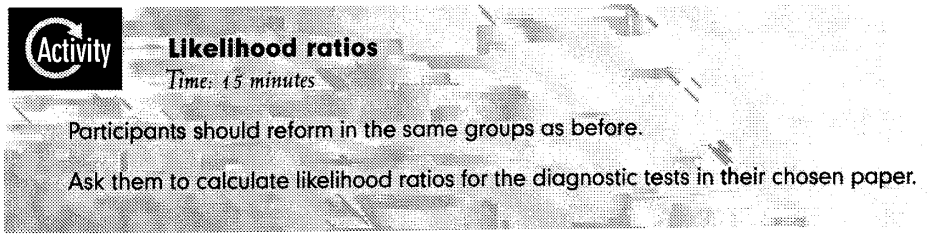
The likelihood ratio of a positive test result is an indication of test performance in correctly identifying the true positives as compared with the false positives.

Likelihood ratio (positive test)

= sensitivity ÷ 1-specificity

= true positive ÷ false positive

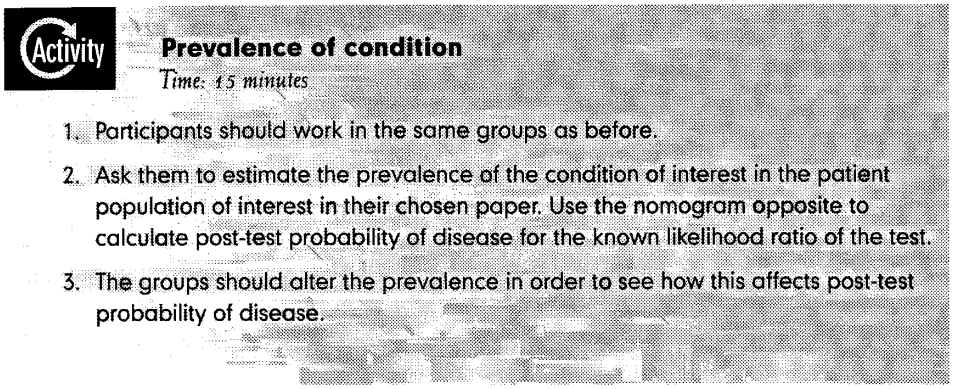
$$= \frac{a \div (a+c)}{b \div (b+d)}$$



Prevalence

Prevalence can be taken into account when assessing the usefulness of a test by applying the likelihood ratio to the pre-test probability (or prevalence) of the disease.

For a given patient, if the disease prevalence is known, it is possible to calculate by how much a positive test result alters the probability of disease in that patient.



Balance between sensitivity and specificity

When considering multiple tests there is often balance between sensitivity and specificity. Sackett *et al.* (1997) recommend the acronyms SpPin and SnNout to distinguish between these properties, see ***Slide 8.5***.

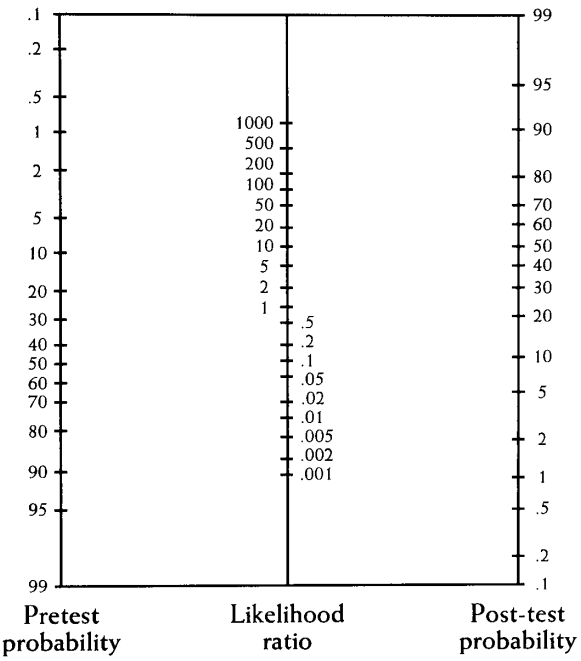
When tests are performed in sequence, the post-test probability of the first test becomes the pre-test probability of the second test.

Assessing the applicability of diagnostic tests

Slide 8.6 brings the consideration of the usefulness of the diagnostic test back to the clinical situation. Refer back to the scenario to get participants to consider whether or not the test would help in the non-research settings in which they practise.

Handout 8.3 shows a checklist for appraising a diagnostic test paper which can either be used as part of the group session or at a later date with feedback the next time the group meets.

Nomogram for interpreting diagnostic test result



A likelihood ratio nomogram. Adapted from Fagan, T. J. (1975) Nomogram for Bayes' Theorem (c). *New England Journal of Medicine* **293** 257.

Reference

Sackett, D. L., Richardson, W. S., Rosenberg, W. & Haynes, R. B. (1997) *Evidence-based Medicine – how to practice and teach EBM*. New York: Churchill Livingstone.

Further Reading

Jaeschke, R., Guyatt, G. & Sackett, D. L. (1994) Users' Guides to the Medical Literature III. How to use an article about a diagnostic test. A. Are the results of the study valid? *JAMA* 271 v 389–91.

Jaeschke, R., Guyatt, G. & Sackett, D. L. (1994) Users' Guides to the Medical Literature III. How to use an article about a diagnostic test. B. What are the results and will they help me in caring for my patients? *JAMA* 271 ix 703–7.

Chapter 9

Decision analysis

Introduction

Many healthcare problems are extremely complex. Supporting evidence may be good for some aspects of the problem but patchy and incomplete for others. There are many different views and values placed on possible outcomes and on which trade-offs are acceptable in achieving different results. Decision analysis provides a framework for considering clinical problems in all their complexity.

This session is structured around a series of exercises which incrementally lead towards participants constructing their own simple decision trees, thereby understanding the principles of what decision analysis sets out to achieve.

Aim

- to give an understanding of the potential role for decision analysis in the clinical context.

Objectives

For participants to:

- become familiar with the terminology used in decision analysis
- understand how a decision tree is constructed
- gain an insight into the debate about applying values to outcomes
- consider possible uses for decision analysis
- feel confident when critically appraising a decision analysis paper with the aid of a checklist.

Timing

Approximately 1 hour.

Materials

- *Slides 9.1, 9.2, 9.3, 9.4, 9.5, 9.6, 9.7, 9.8*
- *Handouts 9.1, 9.2* (enough copies for all participants)
- Flipchart
- Your choice of paper to be critically appraised (enough copies for all participants)
- Calculators – one for each break-out group

Defining decision analysis

A definition of decision analysis is given in ***Slide 9.1***. It can be used before or after the activity set out below.

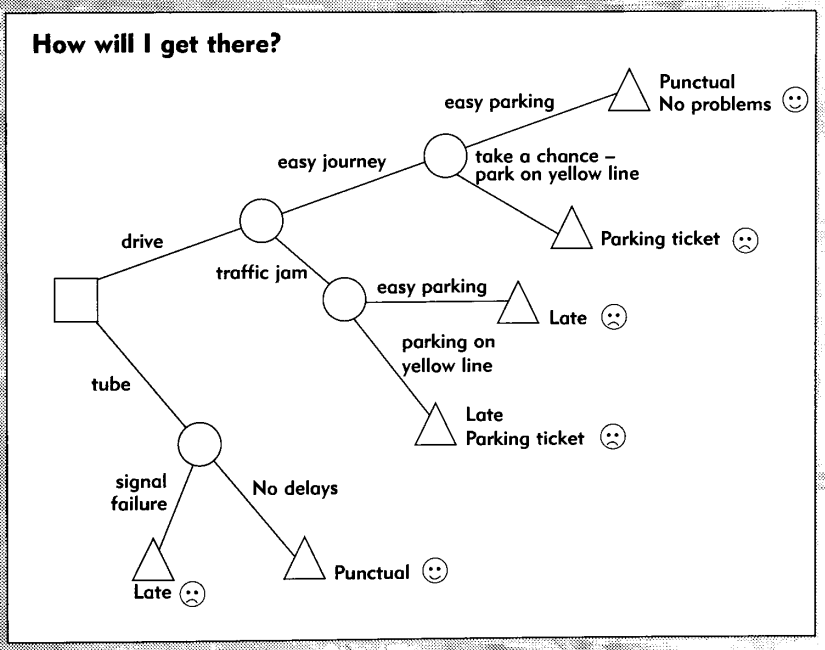
Activity

A simple decision tree

Time: 5 minutes

Draw an example on a flipchart of a simple decision tree similar to the one shown below and shown on **Slide 9.2**.

Use an example from everyday life such as how to get to the workshop venue (choice of transport), deciding whether to get a dog, or buying a car. Gradually draw out the tree, explaining the concepts as you go.



The concepts to get across at this stage include:

- a decision tree maps out the problem
- the tree has a number of different branches
- points of decision are marked by a square
- chance nodes (marked by a circle) show the different options (these are mutually exclusive, with the probability of the events occurring around a chance node adding up to 1)
- outcomes, at the end of each branch, are shown as triangles or rectangles.

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Uses of decision trees

As the basic principles of decision analysis have now been introduced, use ***Slide 9.3***, to summarise the possible uses for decision analysis within the healthcare setting.

Components of decision analysis

Show *Slide 9.4*.

This is a good point to generate a general discussion, asking participants to state what they think the role of decision analysis could be in their work. If you have prior knowledge of the background of the participants, it may be useful for you to have some ideas in case participants are still unsure of where they can use the method.

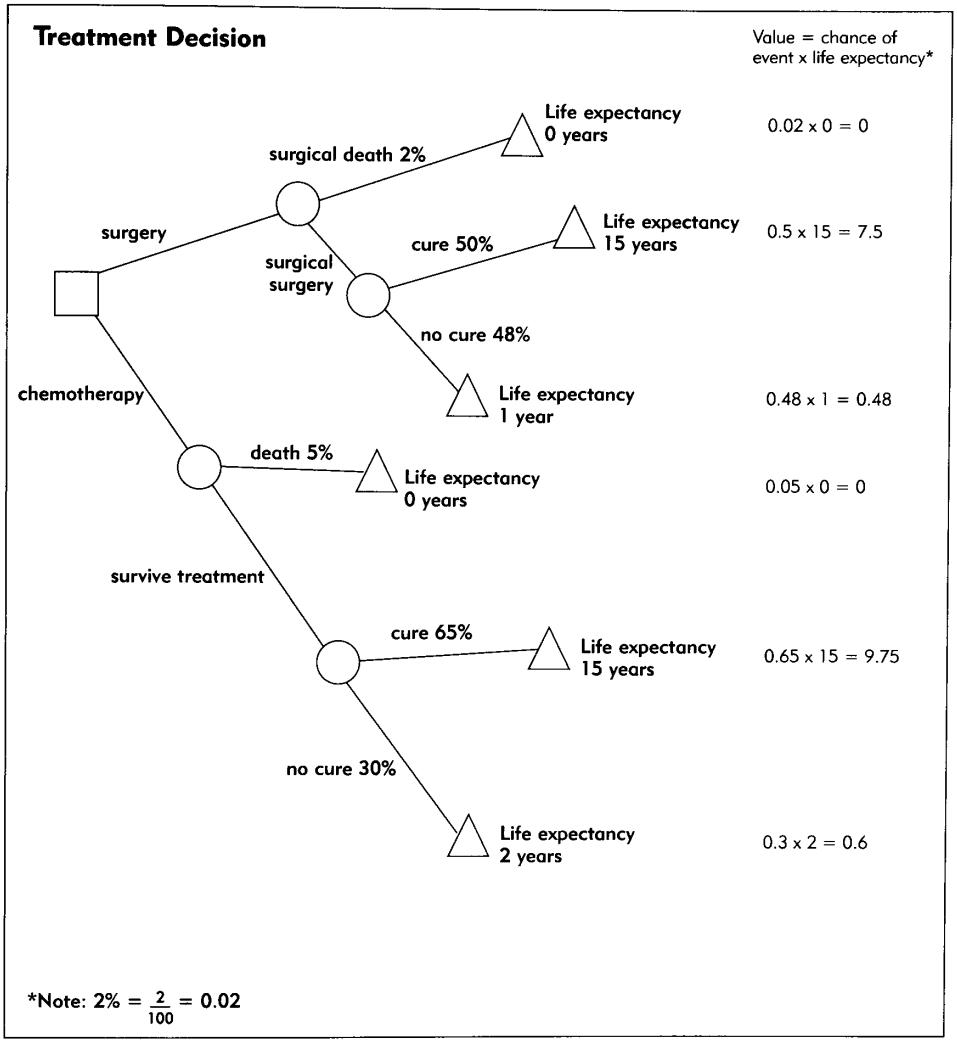
A clinical problem

Time: 10 minutes

Slide 9.5 presents a complex clinical problem. You can use a decision tree to tease out its components and to make explicit what evidence is available to support which parts of the decision process. The method allows for many sources of evidence to be considered (unlike pure critical appraisal which looks at one paper at a time). It also makes transparent the use of values in reaching decisions.

Work this problem through with the group, using the information below, setting the information out as a decision tree on a flipchart.

Treatment decision	Chance	Outcome	Value in terms of life expectancy
Surgery	2% = 0.02	Surgical death	0
	50% = 0.5	Cure; life expectancy 15 years	0.5 × 15 = 7.5
	48% = 0.48	No cure; life expectancy 1 year	0.48 × 1 = 0.48
Chemotherapy	5% = 0.05	Death	0
	65% = 0.65	Cure; life expectancy 15 years	0.65 × 15 = 9.75
	30% = 0.3	No cure; life expectancy 2 years	0.3 × 2 = 0.6



Total value for surgery = 0 + 7.5 + 0.48 = 7.98

Total value for chemotherapy = 0 + 9.75 + 0.6 = 10.35

(Outcomes have been given in terms of life expectancy. These can be used to calculate a value for the different treatment options.)

In this scenario if the only outcome being considered is life expectancy, the decision should be to give chemotherapy.

Group activity: constructing a decision tree

Time: 10 minutes

1. Divide participants into small groups. Make sure each group has a calculator.
2. Distribute **Handout 9.1** containing the scenario.
3. Show the chances associated with different stages of the disease which affect the overall outcome for the patient (also on **Handout 9.1**).
4. On a flipchart the groups should construct a decision tree based on the two treatment options outlined. They should assign probabilities at the chance nodes to calculate the likelihood of the different outcomes. This can either be done calculating the probability of different outcomes for one patient or using whole numbers and calculating for a group of 1,000 women in each treatment arm.

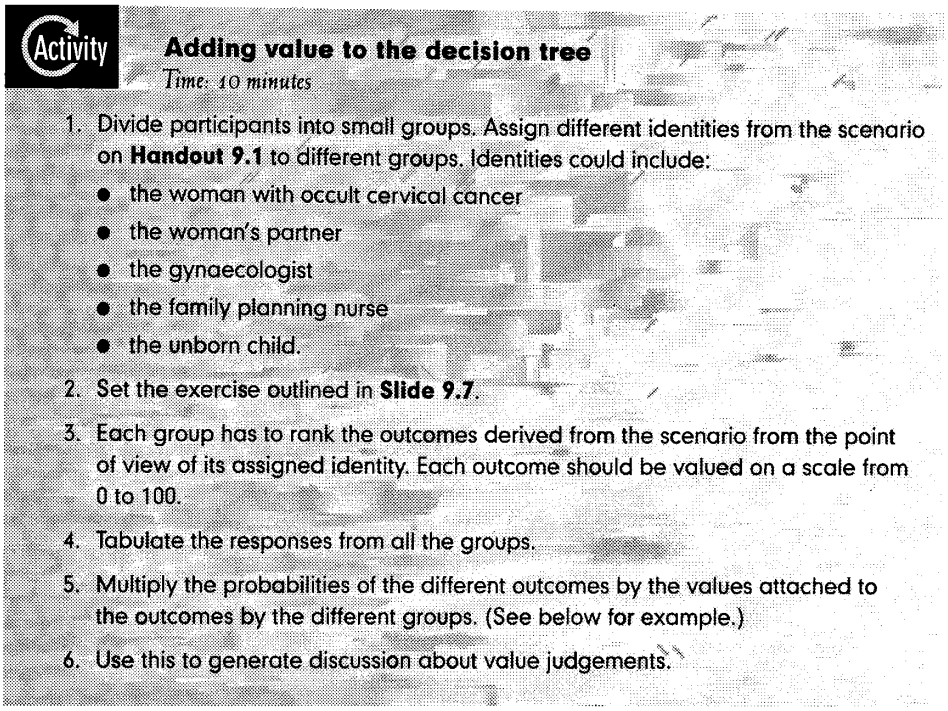
Methods of reaching a decision

It is rare that a decision is based on outcome, ie survival, alone. ***Slide 9.6*** lists some of the different ways of assigning values to outcomes. The standard survey instruments listed have all been validated and shown to be reliable and responsive to changes in a person's condition.

Multiple gamble techniques require us to ask the respondent to consider the choice between living the rest of their life in a particular condition and taking a 'gamble' with a treatment that either restores them to perfect health or kills them. The chances of full health or death are then varied until the point is identified at which the patient decides the gamble is not worth taking.

Using scales to reach a decision

Rating scale measurements can readily be used in a clinical setting to gauge an individual patient's preferences. The scale may be a straight line between perfect health and death, with the patient placing the health state being discussed, ie the preferred one, along that line. Professor David Sackett draws a thermometer and asks the patient to rank the outcome preferences between 0 and 100.



Activity **Adding value to the decision tree**

Time: 10 minutes

1. Divide participants into small groups. Assign different identities from the scenario on **Handout 9.1** to different groups. Identities could include:
   - the woman with occult cervical cancer
   - the woman's partner
   - the gynaecologist
   - the family planning nurse
   - the unborn child.
2. Set the exercise outlined in **Slide 9.7**.
3. Each group has to rank the outcomes derived from the scenario from the point of view of its assigned identity. Each outcome should be valued on a scale from 0 to 100.
4. Tabulate the responses from all the groups.
5. Multiply the probabilities of the different outcomes by the values attached to the outcomes by the different groups. (See below for example.)
6. Use this to generate discussion about value judgements.

How different values weight outcomes values

	Group 1		Group 2	
Probability of outcome	Value	Value x probablity of outcome	Value	Value x probablity of outcome
Outcome 1 (y)	a	a × y	c	c × y
Outcome 2 (z)	b	b × z	d	d × z
etc				
Total weighted value	add these		add these	

Summary: the rationale for using a decision analysis approach

Use *Slide 9.8* to summarises the rationale for using a decision analysis approach, before moving on to the critical appraisal of a decision analysis article.

Critical appraisal of a decision analysis paper

Time: 15 minutes

1. Divide participants into small groups.
2. Provide them with copies of **Handout 9.2 Checklist for appraising a decision analysis paper.**
3. Ask them to critically appraise the chosen paper from the suggestions below.
4. Bring the participants back together to feedback answers, and generate discussion.

If time is short you could ask each group to answer different questions from the checklist.

This exercise can be done away from the group setting in which case it can be used as a discussion point the next time the group meets.

Some suggested papers

Fletcher, J., Hicks, N. R., Kay, J. D. S. & Boyd, P. A. (1995) Using decision analysis to compare policies for antenatal screening for Down's Syndrome. *British Medical Journal* **311** 351–6.

Downs, S. M., McNutt, R. A. & Margolis, P. A. (1991) Management of infants at risk for occult bacteremia: a decision analysis. *Journal of Paediatrics* **118** 11–20.

Simes, R. J. (1985) Treatment selection for cancer patients: application of statistical decision theory to the treatment of advanced ovarian cancer. *Journal of Chronic Disease* **38** ii 171–86.

Further reading

Llewelyn, H. & Hopkins, A. (Eds) (1993) *Analysing How We Reach Clinical Decisions*. London: Royal College of Physicians.

Richardson, W. S. & Detsky, A. S. (1995) Users' Guides to the Medical Literature VII. How to use a clinical decision analysis. A. Are the results of the study valid? *JAMA* 273 xvi1292–5.

Richardson, W. S. & Detsky, A. S. (1995) Users' Guides to the Medical Literature VII. How to use a clinical decision analysis. B. What are the results and will they help me in caring for my patients? *JAMA* 273 xx1610–3.

Thornton, J. G., Lilford, R. J. & Johnson, N. (1992) Decision analysis in medicine. *British Medical Journal* **304** 1099–103.

Thornton, J. G., Lilford, R. J. & Johnson, N. (1995) Decision analysis in medicine. *British Medical Journal* **310** 791–4.

Chapter 10

Economic analysis

Handout Masters

OHP Masters

Introduction

There are finite resources available for the NHS so there is an increasing emphasis on getting the best value in terms of health gain from that money. The language of economic analysis is being applied increasingly to healthcare and questions are being asked such as:

- is this treatment cost-effective?
- will generic prescribing reduce the drug budget?
- are there enough Quality Adjusted Life Years (QUALYs) gained from kidney transplants for elderly patients, or would it be better to put the money into coronary angioplasty?

Aim

- to introduce some of the key concepts of economic analysis to assist with basic appraisal of an economic analysis article.

Objectives

For participants to:

- understand what is meant by the terms 'economic analysis', 'opportunity cost', 'cost minimisation', 'cost effectiveness', 'cost utility' and 'cost benefit'
- be able to appraise an economic analysis article using a checklist.

Timing

Approximately 1½ hours.

Materials

- *Slides 10.1, 10.2*
- *Handouts 10.1, 10.2* (enough copies for all participants)
- Your choice of paper to be critically appraised (enough copies for all participants)
- Flipchart

Economic analysis

Firstly, the question 'What is economic analysis?' needs to be addressed.

Show ***Slide 10.1 What is economic analysis?***

There are two points mentioned here:

- it is a technique which can help assist decision-making when choices have to be made owing to the finite resources available for the NHS
- it helps to define resource allocation.

Opportunity cost

The concept of opportunity cost is defined in ***Slide 10.2***.

Opportunity cost is fundamental to economic evaluation. In situations where resources are finite, as in healthcare, allocating resources for one purpose means that the opportunity to use them for something else is lost.

So why do we need economic analysis?

Economic evaluation provides a framework that can be used to assist in decision-making. The rationale is to maximise the benefit to society from the resources available. The method is particularly valuable when allocating scarce resources between competing claims.

Methodologies used in economic analysis

These are the four main methodologies used in economic analysis outlined in ***Handout 10.1.*** which also includes exercises to illustrate the key principles of each of these methodologies as well as a definition for each of them.

Cost minimisation exercise

Time: 5 minutes

Handout 10.1, Exercise 1

1. Divide the participants into small groups.
2. Present the exercise.
3. Encourage participants to work through the maths (see below), working out the cost for a course of treatment. It may be helpful for the group if you allow them a few minutes and then work the example through on a flipchart. Although drug A is cheaper per day, drug B is cheaper per course (and a shorter length of treatment will aid compliance!). The fixed budget will buy more courses of drug B. Alternatively, if 70 patients need treatment, there will be greater savings if drug B is the preferred treatment.

Drug	Cost per course of treatment	Number of courses purchased for £5,000	Cost of 70 courses
A	7 × £10 = £70	71 courses and £30 change	£4,900
B	4 × £15 = £60	83 courses and £20 change	£4,200

It is useful to follow up this exercise by drawing attention to the definition of cost minimisation given in *Handout 10.1*.

Cost effectiveness exercise

Time: 10 minutes

Handout 10.1, Exercise 2

This exercise illustrates some of the principles of cost effectiveness analysis, introducing the idea that costs can be linked to outcomes of treatment.

1. Divide the participants into their small groups.
2. Present the exercise.
3. Encourage participants to work through the maths (see opposite). It may be helpful for the group if you allow them a few minutes and then work the example through on a flipchart.

	Option 1	Option 2
Cost per try	£2,500	£1,500
Success rate (chance of pregnancy)	1 in 2	1 in 4
Number of treatment cycles for £45,000	18	30
Number of pregnancies for £45,000	9	7.5
Cost per pregnancy	£5,000	£6,000

A definition for cost effectiveness analysis is given in *Handout 10.1*.

Use this to emphasise the differences between cost minimisation and cost effectiveness, ie the latter includes outcome measures.

Cost utility analysis exercise

Time: 15 minutes

Handout 10.1, Exercise 3

This exercise illustrates the principles of cost utility analysis, using the Quality Adjusted Life Year as an example. This enables comparisons to be made between different procedures.

A number of questionnaires have been developed to measure overall health status. These include the SF-36, the Nottingham Health Profile and the Euro-Qol. Other such utility measures include healthy year equivalents.

The scenario in this exercise requires participants to work through the given figures in order to generate a discussion about prioritisation on the basis of a common outcome measure that is comparable across different procedures.

1. Divide the participants into small groups.
2. Present the exercise.
3. Participants should be encouraged to:
   - calculate the total cost for purchasing each procedure for all waiting patients
   - calculate the total number of QUALYs bought for all patients waiting for that procedure
   - calculate the cost per QUALY.
4. It may be helpful for the group if you allow them a few minutes and then work the example through on a flipchart (see page 98).
5. The discussion can focus on which combination of procedures can be bought for the limited budget.

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Answers for cost utility exercise

Procedure	Number waiting	Cost per item	QUALY per item	Total cost	Total QUALYs	Cost per QUALY
A	20	£500	10	£10,000	200	£50
B	25	£2,000	10	£50,000	250	£200
C	5	£2,500	20	£12,500	100	£125
D	15	£1,500	15	£22,500	225	£100
E	10	£1,000	8	£10,000	80	£125
Totals	**75**			**£105,000**	**855**	

A definition for cost utility is given in *Handout 10.1*. Use this to highlight how this analysis differs from the previous two, ie cost utility analysis combines mortality and morbidity into a single measure.

Some real examples of costs per QUALY are given in *Handout 10.1*.

Cost-benefit analysis exercise

Time: 15 minutes

Handout 10.1, Exercise 4

This exercise illustrates the principles of cost-benefit analysis which is considered to be the 'gold standard' of economic analysis.

1. Divide the participants into small groups.
2. Present the exercise.
3. Invite participants to think about the direct and indirect costs and benefits of different models of healthcare delivery. The costs and benefits, both tangible and intangible, should be considered from different perspectives. These include the patient, the healthcare setting and the wider society (including carers).

   Participants can use the grid ***Answer format for cost-benefit exercise*** on ***Handout 10.1*** to help them to think systematically about the different costs and benefits attached to different models of healthcare delivery.

Tip **A definition of cost benefit analysis is given in *Handout 10.1*.**

Use this to re-emphasise why cost benefit is considered to be the gold standard of economic analysis.

Activity **Critical appraisal of an economic analysis paper**

Time: 20 minutes

1. Divide participants into small groups.
2. Provide them with copies of **Handout 10.2 Checklist for an economic analysis paper**.
3. Ask them to critically appraise your choice of an economic analysis paper – see below for suggestions.
4. Bring the participants back together to feedback answers, and generate discussion.

Tip **If time is short you could ask each group to answer different questions from the checklist.**

This exercise can be done away from the group setting in which case it can be used as a discussion point the next time the group meet.

Some suggested papers

Creed. F., Mbaya, P., Lancashire, S., Tomenson, B., Williams, B. & Holme, S. (1997) Cost effectiveness of day and inpatient psychiatric treatment: results of a randomised controlled trial. *British Medical Journal* **314** 1381–5.

Brown, J., Bryan, S. & Warren, R. (1996) Mammography screening: an incremental cost effectiveness analysis of double versus single reading of mammograms. *British Medical Journal* **312** 809–12.

Pharoah, P. D. P. & Hollingworth, W. (1996) Cost effectiveness of lowering cholesterol concentrations with statins in patients with and without pre-existing coronary heart disease: life table method applied to health authority population. *British Medical Journal* **312** 1443–8.

Further reading

Drummond, M. F., Richardson ,W. S., O'Brien, B. J. & Levine, M. (1997) Users' Guides to the Medical Literature XIII. How to use an article on economic analysis of clinical practice. A. Are the results of the study valid? *JAMA* **277** xix1552–7.

Eddy, D. M. (1992) Cost effectiveness analysis. A conversation with my father. *JAMA* **267** xii 1669–75.

O'Brien, B. J., Heyland, D., Richardson, W. S., Levine, M. & Drummond, M. F. (1997) Users' Guides to the Medical Literature XIII. How to use an article on economic analysis of clinical practice. B. What are the results and will they help me in caring for my patients? *JAMA* **277** xxii 802–6.

Mooney, G. (1992) *Economics, Medicine and Health Care* (2nd edition). Hemel Hempstead: Harvester Wheatsheaf.

Robinson, R. (1993) Economic evaluation and health care. What does it mean? *British Medical Journal* **307** 670–3.

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Part 3

Tools for ensuring best practice

Chapter 11

Local implementation of evidence based practice

Handout Masters

OHP Masters

Introduction

So far we have considered the skills required for ensuring best care. The next two chapters concentrate on how practice can be changed to be evidence-based. This chapter looks at implementation strategies, and how best to plan getting evidence into everyday practice. There are already many guidelines, standards and care pathways available that may be appropriate to use in your local setting. This chapter will look at:

- the strategies available
- critical appraisal of published work
- how to adapt these for local use.

Aim

- to consider the implementation of evidence based practice in their local setting.

Objectives

For participants to:

- consider how clinical decision-making can be influenced by an:
  - individual
  - clinical team
  - organisation
- consider how to best use evidence in a local setting.

Timing

Approximately 20 minutes.

Materials

- *Slides 11.1, 11.2*
- Flipchart

Notes on use

This chapter gives a brief introduction to levels of implementation, and is intended as a preface to any of the following chapters in **Part Three**. These chapters will look in more detail at individual methods of the implementation of evidence into practice.

It can also be useful to invite relevant postholders to talk about what is happening locally to add to the relevance of the chapters in this section. Good examples of the people who might contribute would be a representative from audit, or the lead for guideline development or clinical governance.

Local implementation

Levels of implementation

Implementation of evidence needs to happen at an individual, team and organisational level in order to ensure effective clinical care. Each level is represented in the Venn diagram shown in ***Slide 11.1***.

As an individual you can ask the question, 'What do I need to know about this patient?' An educational prescription – that is keeping a record of patient problems as they arise – and allocating these clinical problems to specified learners who then have a responsibility to search out the evidence around the posed problem, can be used as a reminder, to ensure that outstanding patient problems are acted upon.

It is important that individuals become involved with the decision-making of clinical teams. Journals clubs and grand rounds based on current clinical cases provide an opportunity for multi-disciplinary teams to study the recent evidence upon which to base clinical decisions.

The promotion of evidence based practice needs to be linked to educational programmes in order to ensure staff development. EBP skills need to be taught, with an emphasis on solving real problems and improving patient care.

Audit can be used by clinical teams to assess the effectiveness of an evidence based standard, and at an organisational level determine clinical priorities.

Evidence based guidelines and standards are best introduced throughout an organisation to ensure effective and efficient care.

Finally, an evidence based care pathway will link individual patient need with an organisational approach for effective care.

It is important to remember that an infrastructure needs to be available within the clinical area before EBP can start. All need to be underpinned by library, information and IT, and by support from stakeholders.

Local implementation

Much evidence based information is already available so it is not always necessary to start from scratch. We will go on to look at published guidelines and care pathways that may well be adaptable for local needs. The steps below which are needed to adapt these are outlined in ***Slide 11.2***.

Disseminate

It is important to identify all people who will be affected by a proposed change in order to ensure that they are kept informed at all stages. Firstly, disseminate the proposed documents that have led you to believe that a change in practice is necessary to improve patient care.

Adapt

Careful consideration needs to be given to your local population and staff. Implementation strategies then need to be adapted to meet patient needs and be realistic with the skills mix available.

Adopt

Involved staff need to adopt new ways of thinking about patient care. This can be a difficult phase when implementing change and will be considered further in the chapter on managing change (***Chapter 17***).

Implement

To implement a change in practice it is often best to pilot it with a small group who are keen to see the change happen. Once the pilot has been successfully implemented, wider use may then be considered.

Monitor and evaluate

It is important to set down what you hope to achieve through a change in practice so that you can ensure that you achieved what you set out to do. Baseline information needs to be collected and outcomes measured subsequently. This will be considered further in the audit and outcomes workshop.

Further reading on implementation

Appleby, J., Walshe, K. & Ham, C. (1995) *Acting on the Evidence*. NAHAT Research paper no 17. Birmingham: NAHAT.

Campbell, H., Hotchkiss, R., Bradshaw, N. & Parteons, M. (1998) Integrated Care Pathways. *British Medical Journal* **316** 133–137.

Dunning, M., Abi-Aad, G., Gilbert, D., Gillam, S. & Livett H. (1998) *Turning Evidence into Everyday Practice*. Interim report from the PACE programme. London: King's Fund.

Feder, G., Griffiths, C., Highton, C., Eldridge, S., Spence, M. & Southgate, L. (1995) Do clinical guidelines introduced with practice based education improve care of asthmatic and diabetic patients? A randomised controlled trial in general practices in East London. *British Medical Journal* **311** 1473–1478.

Grimshaw, J., Freemantle, N., Wallace, S., Russell, I., Hurwitz, B., Watt, I., Long, A. & Sheldon, T. (1995) Developing and implementing clinical practice guidelines. *Quality in Health Care* **4** 55–64.

Grimshaw, J. M. & Russell, I. T. (1993) Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet* **342** 1317–1322.

Haines, A. & Jones, R. (1994) Implementing findings of research. *British Medical Journal* **308** 1488–1492.

Murphy, M. & Dunning, M. (1997) Implementing clinical effectiveness – is it time for a change of gear? *British Journal of Health Care* **3** (1) 23–26.

National Audit Office (1995) *Clinical audit in England*. London: HMSO.

NHS Centre for Reviews and Dissemination (1994) Implementing clinical practice guidelines. *Effective Health Care Bulletin Number 8*.

NHSE (November 1997) *Clinical Effectiveness Resource Pack*.

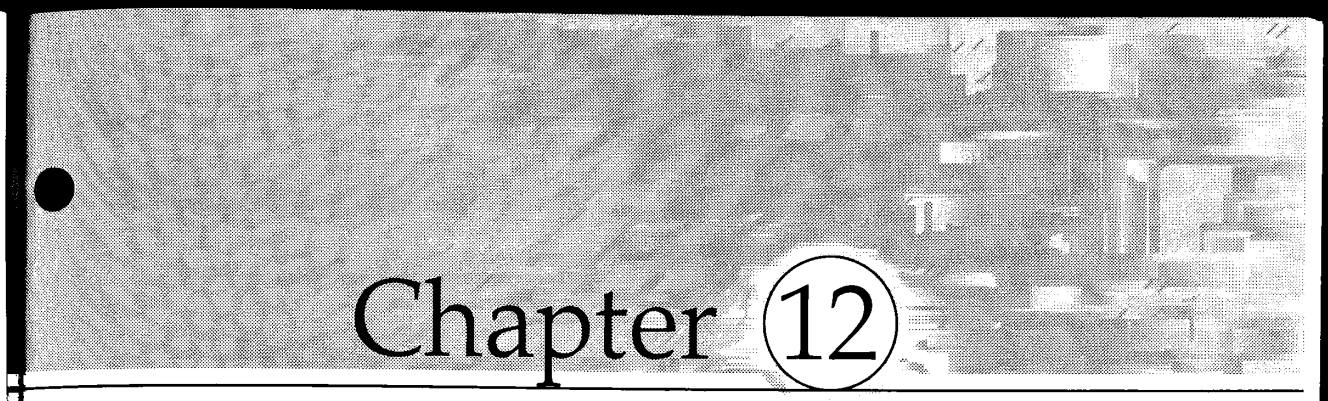
NHSE (January 1996) *Promoting Clinical Effectiveness. A framework for action in and through the NHS*.

NHSE (May 1996) *Clinical Guidelines. Using clinical guidelines to improve patient care within the NHS*.

Oxman, A. D., Thomson, M. A., Davis, D. A. & Haynes, R. B. (1995) No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. *Canadian Medical Association Journal* **153** 10 1423–1431.

Stocking, B. (1992) Promoting change in clinical care. *Quality in Health Care* **1** 56–60.

Thomson, R., McElroy, H. & Sudlow, M. (1998) Guidelines on anticoagulant treatment in atrial fibrillation in Great Britain: variation in content and implications for treatment. *British Medical Journal* **316** 509–513.



Chapter 12

Guidelines

Handout Masters

OHP Masters

Introduction

Guidelines have been part of clinical decision-making for many years. However, with the advent of evidence based practice, they can be a useful tool in ensuring best practice. It is important that they are critically appraised since many are not evidence-based.

Guidelines also tell us which interventions are effective in a population, but it is important that there is flexibility to allow for patient preference and to meet specific needs.

The main purpose of guidelines is to make evidence based standards explicit and accessible in order to make clinical decision-making easier and more objective. They also provide a basis for assessing professional performance and should aim to educate both professionals and patients about best care.

Aims

- to consider the concept of clinical guidelines
- to consider the information required for critical appraisal
- to explore important factors in ensuring their successful implementation.

Objectives

For participants to:

- understand what clinical guidelines are
- appreciate key factors which are important when appraising a guideline

- practise using guidelines to answer patient and clinician questions
- consider the process required to adapt and implement guidelines locally.

Timing

Approximately 1½ hours.

Materials

- *Slides 12.1, 12.2, 12.3*
- *Handout 12.1* (enough copies for all participants)
- Your choice of paper to be critically appraised (enough copies for all participants)
- Flipchart

The session works well if, in addition to this presentation, local practice is described by a representative working on guideline development and implementation in the trust. The brief for the local presenter should be to describe the work that is being carried out on guidelines in the trust. This should be covered in no more than 15 minutes (plus 5 minutes for questions).

Guidelines

Start by showing ***Slide 12.1*** which gives a definition of guidelines. Since clinical guidelines have been around for many years, participants will have some knowledge as to what they are.

People react very differently when faced with clinical guidelines. Some welcome them with open arms, some pay lip service to them being a valuable asset, but file them away carefully never to refer to them again, and others strongly dislike them. It can sometimes be easy to lose sight of what the aims of clinical guidelines are, some of which are listed in ***Slide 12.2***.

Appraising guidelines

Time: 25 minutes

In reality not all clinical guidelines are reliable, valid or transferable to other settings. Typically, they may not be based on current best evidence but on current local practice and many do not allow for patient preferences. You may find this activity useful to get participants thinking about what is important in clinical guidelines.

1. In small groups, ask participants to identify the key factors which they would consider to be important when appraising guidelines. Show **Slide 12.3**.
2. Allow about 10 minutes and then ask all the groups to share their responses and note these on a flipchart. Bring up the following points, if they are not covered by participants.

Key factors which you would consider to be important in guidelines

- are they evidence based?
- will they benefit the patient?
- are they endorsed by relevant professional bodies?
- were appropriate professionals/patients involved?
- who wrote them, why, and who paid?
- is there information on costs and benefits?
- were they peer reviewed and piloted?
- are they clear and easy to use?
- are they applicable locally?
- are monitoring/audit criteria included?

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Factors for guidelines to be effective

A systematic review carried out by Grimshaw and Russell (1993) concluded that the probability of guidelines being effective in helping to change clinical practice and improve patient outcomes depended on three factors, as shown in ***Slide 12.3***.

It may be helpful to raise the following key points with the group:

- **guidelines need to be adapted to fit local circumstances, without loosing the evidence base. This adaptation needs to be carried out by a local champion together with as many end users as possible**
- **it is important that dissemination is carried out by active educational intervention, using as many different approaches as possible**
- **guidelines should be implemented as part of professional activity. This may mean a change in medical record keeping, or the use of computerised record keeping which can alert clinicians to appropriate guidelines. Another approach is to use patient-mediated interventions, in which the aim is to affect professional practice through informing patients.**

Critical appraisal of paper on guidelines

Time: 20 minutes

1. Divide participants into small groups.
2. Provide them with copies of **Handout 12.1 Checklist for appraising a guideline.**
3. Ask them to critically appraise a paper of your choice (see below for suggestions)
4. Bring the participants back together to feedback answers, and generate discussion.

If time is short you could ask each group to answer different questions from the checklist.

This exercise can be done away from the group setting in which case it can be used as a discussion point the next time the group meets.

Suggested papers for appraisal

Eccles, M., Freemantle, N. & Mason, J. (1998) North of England evidence-based guideline for non-steroidal anti-inflammatory drugs versus basic analgesia in treating the pain of degenerative arthritis. *British Medical Journal* **317** 526–30.

RCN Institute. Centre for Evidence Based Nursing, University of York. School of Nursing, Midwifery and Health Visiting, University of Manchester (1998) *The management of patients with leg ulcers.* RCN Publishing.

Reference

Grimshaw, J. & Russell, I. (1993) Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet* **342** 1317–22.

Further reading

Cook, D. J., Greengold, N. L., Ellrodt, A. G. & Weingarten, S. R. (1997) The relation between systematic reviews and practice guidelines. *Annals of Internal Medicine* **127** (3) 210–216.

Duff, L. A., Kitson, A. L., Seers, K. & Humphries, D. (1996) Clinical guidelines: an introduction to their development and implementation. *Journal of Advanced Nursing* **2** 887–895.

McClarey, M. & Duff, L. (1997) Making sense of clinical guidelines. *Nursing Standard* **12** (1) 34–36.

Tingle, J. (1997) Clinical guidelines: legal and clinical risk management issues. *British Journal of Nursing* **6** (11) 639–641.

Chapter 13

Integrated care pathways

Handout Masters

OHP Masters

Introduction

Integrated Care Pathways (ICPs) are like guidelines. They are documents based on evidence, current practice and patient needs. They are designed to decrease variation in practice patterns.

However, unlike guidelines, ICPs become part of the integral care of patients since they form their 'clinical' records. These records are then used by all professions.

Total Quality Management (an industry technique) teaches that the most effective way to improve the quality of a service is to reduce the variation in its delivery. ICPs are such an approach: their use has been shown to reduce variation in clinical processes and to improve the quality of patient care, whilst decreasing the length of stay in hospital.

Aim

- to understand the basic principles of care pathways and their role in the implementation of evidence based practice.

Objectives

For participants to:

- understand what care pathways are
- appreciate key factors which are important in care pathway development
- consider the main advantages, disadvantages, and areas of work where a care pathway may help.

Timing

Approximately 45 minutes.

Materials

- *Slides 13.1, 13.2, 13.3*
- *Handouts 13.1, 13.2* (enough copies for all participants)
- Flipchart
- An example of a local ICP

This session works well if, in addition to this presentation, local practice is described by a representative working on care pathways in the trust. The brief for a local presenter would be to describe the work that is being carried out on ICPs in the trust, which should be covered in no more than 15 minutes (plus 5 minutes for questions).

Not all participants will be familiar with ICPs. It may therefore be useful to ask who has used them, and what their feelings are about them. This will let you gauge the level of understanding within the group and will help you pitch this session at the most appropriate level.

This session should give enough background information to allow participants to discuss what they feel are the potential benefits and disadvantages of ICPs.

Integrated Care Pathways

Definition

A definition of integrated care pathways is given in ***Slide 13.1***.

ICPs should always be based on evidence, current practice and patient need. Their purpose is to decrease variation in clinical processes and thus to improve patient care. They delineate the entire plan of care for treating a given diagnosis or procedure during the patient's admission. ICPs can also incorporate guidelines for specific aspects of care, eg antibiotic selection for urinary tract infection.

Other names for ICPs

ICPs are known by many names.

Slide 13.1 shows some of the alternative terms. Ask the participants if they are aware of any other names.

Functions of an ICP

Next, consider what an ICP does. Show ***Slide 13.2***. The points are amplified below:

An ICP:

Automatically becomes part of care

An ICP should be used as a unitary multi-disciplinary record, used by all professionals to deliver specified care. It should be kept at the end of the patient's bed or an agreed central location.

Divides care into time intervals during which specific tasks are indicated to achieve goals/outcomes

It is important to document what the aims of interventions are in terms of patient outcomes.

Outlines care for the whole multi-disciplinary team

The document is divided into time intervals, usually days (but may be hours, eg for day surgery; or weeks, eg for stroke rehabilitation) during which specific tasks are indicated for the multi-disciplinary team. Everybody in the team should contribute actively towards recovery.

Encourages discharge planning

Discharge planning should be built into ICPs.

Allows for variation

ICPs acknowledge that variations in care occur. An ICP is not set in stone, variations are permitted.

Includes patient protocols

ICPs should include patient protocols. These are simplified ICPs with less jargon. The simpler language helps increased patient awareness of what to expect during a stay in hospital.

Research protocols can be included

Where there is uncertainty about best treatment, research protocols can be built into ICPs.

Pre-requisites for an ICP

There are also certain prerequisites for an ICP, listed in ***Slide 13.3***.

It may be useful at this stage to show an example of a local ICP, so participants can see what they look like and how they are used in the local setting.

Developing ICPs

Now that you have considered what is meant by an ICP, and looked at what they do, it will be useful to outline the steps that are involved in developing ICPs. These are outlined in ***Handout 13.1***. Distribute this and run through the points in it.

ICP benefits and drawbacks

Time: 15 minutes

1. Divide the participants into small groups.
2. Ask them to think of an area where it may be appropriate to use an ICP and then discuss the following questions:
   - what do you see as the benefits of an ICP?
   - what do you see as the drawbacks of an ICP?
   - in which areas of your work might an ICP be helpful?
3. Bring the group back together and take feedback in order to generate discussion about their suggestions.

Remember, when discussing the disadvantages, that the main aim is to improve patient care.

To conclude the session, distribute **Handout 13.2**. This outlines the main advantages that have been demonstrated by clinical research. This can be used to draw together the points raised in the group work.

Handout Masters

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Chapter 14

Audit

Handout Masters

OHP Masters

Introduction

Is current practice in line with the evidence? If not, what can we do about it? This is the problem in a nutshell. Audit is a tool to help resolve that problem.

Clinical audit has been a requirement in the NHS since the late 1980s. Much effort has gone into developing programmes and an infrastructure for carrying out audit projects. But how many projects close the loop and are effective in bringing about change?

Aim

- to understand the role of audit in monitoring the processes and outcomes of care, so ensuring that local practice accords with best evidence of effectiveness instilled in guidelines.

Objectives

For participants to:

- understand audit methodology and to be able to distinguish it from research
- appreciate the importance of generating meaningful criteria for audit and standards based on best evidence of effectiveness
- be able to critically appraise an audit paper, determining what has been audited, how the audit was carried out and the validity of the results
- feel confident in using audit as a tool to monitor the implementation of local guidelines and to determine the outcomes of care.

Timing

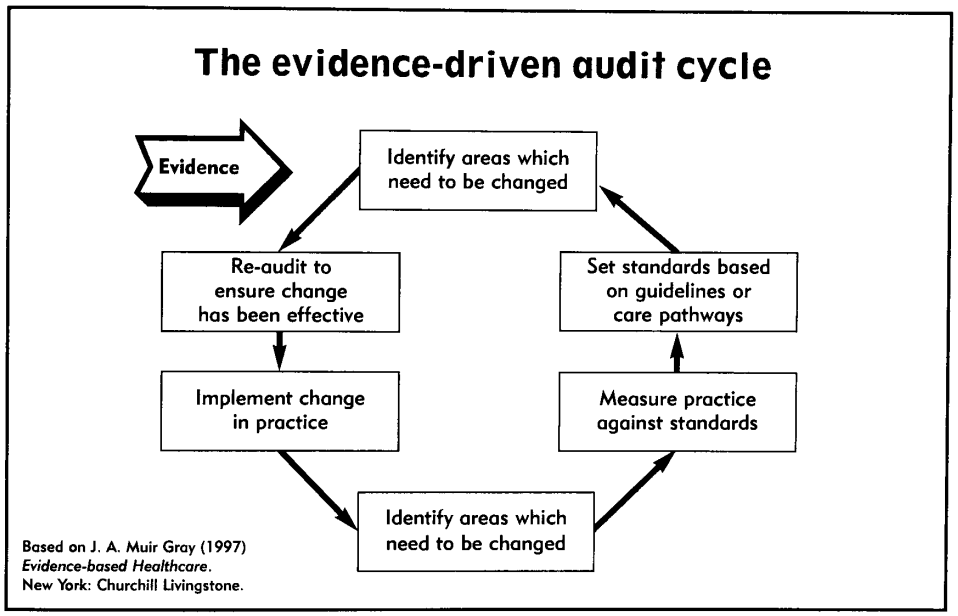
Approximately 1 hour.

Materials

- *Slides 14.1, 14.2*
- *Handouts 14.1, 14.2* (enough copies for all participants)
- Your choice of paper to be critically appraised (enough copies for all participants)
- Flipchart

Background

This section sets out one way of teaching the concepts of audit in the context of critically appraising a published article. Particular emphasis is given to the definition of standards, which is when best evidence of effectiveness should be determined. The audit process then allows current practice to be assessed against those evidence based standards. The audit loop is closed with the measurement of outcomes resulting from any changes that have been implemented. Audit is therefore a tool for change.



Tip

The session works well if, in addition to this presentation, local practice is described by an audit representative working in the trust. The person might be the chair of the audit committee, the head of the audit department or a lead clinician in audit.

The brief for a local presenter would be to consider, in no more than 15 minutes (plus 5 minutes for questions) the local audit facilities and support available for staff, the audit cycle and the use of evidence to generate standards, and to outline a local example which completed the audit cycle.

The session then continues with the critical appraisal of an audit paper, with a detailed consideration of the importance of setting the right standards.

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Audit – a tool for getting evidence into practice

Stages in audit

The diagram on ***Slide 14.1*** shows evidence coming in at the top to help identify the topic – evidence should be incorporated into the audit cycle. However it is also vital that it plays a major part in setting the standards based on care pathways or guidelines.

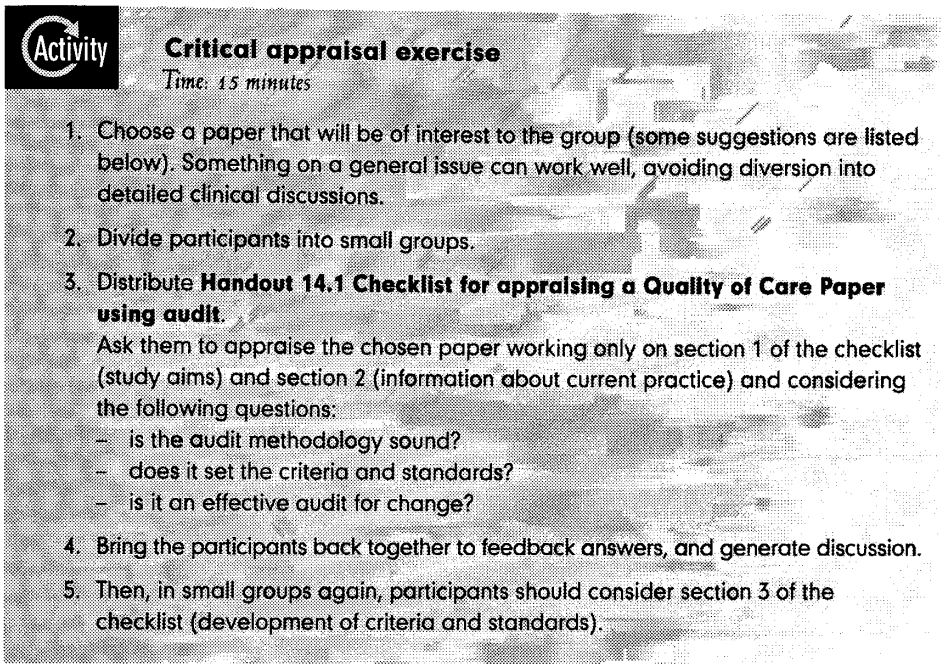
The session can be introduced by outlining the important stages in audit, especially the fact that it is important to get baseline data to know where practice is in comparison with the standards identified in the audit tool.

Re-audit

If there are areas that need to be changed, it is important to re-audit once the change has been implemented to check the change has had the desired effect on the relevant outcome.

Audit and research – the difference

One question that is frequently asked is what the difference is between audit and research. A simplistic answer is shown in ***Slide 14.2***.



Activity

Critical appraisal exercise

Time: 15 minutes

1. Choose a paper that will be of interest to the group (some suggestions are listed below). Something on a general issue can work well, avoiding diversion into detailed clinical discussions.
2. Divide participants into small groups.
3. Distribute **Handout 14.1 Checklist for appraising a Quality of Care Paper using audit.**
   Ask them to appraise the chosen paper working only on section 1 of the checklist (study aims) and section 2 (information about current practice) and considering the following questions:
   - is the audit methodology sound?
   - does it set the criteria and standards?
   - is it an effective audit for change?
4. Bring the participants back together to feedback answers, and generate discussion.
5. Then, in small groups again, participants should consider section 3 of the checklist (development of criteria and standards).

Tip

If time is short you could ask each group to answer different questions from the checklist.

This exercise can be done away from the group setting in which case it can be used as a discussion point the next time the group meets.

Some suggested papers

1. Penney, G. C., Glasier, A. & Templeton, A. (1994) Multicentre criterion based audit of the management of induced abortion in Scotland. *British Medical Journal* **309** 15–18.
2. Mahendra, M. & Lant, A. (1997) Inter-practice audit of diagnosis and management of hypertension in primary care: educational intervention and review of medical records. *British Medical Journal* **314** 942–946

Handout Masters

OHP Masters

Criteria setting

Time: 15 minutes

Use the same paper chosen for the previous activity.

1. Divide participants into small groups.
2. Distribute **Handout 14.2** and assign each group a different professional role.
3. Ask each group to look closely at the audit criteria set out in the paper, from their group's perspective, using the questions in **Handout 14.2**.

Bring the groups back together for discussion.

1. Start with the listing of each group's responses to the questions about the chosen audit criteria, including whether any criteria should be omitted or added. This should highlight the different perspectives of different professional and user groups when considering the criteria to judge the appropriateness of services.
2. Lead into a discussion about evidence as the basis for developing standards.
3. Make the link back to evidence based guidelines and care pathways from which local standards should be generated.

Standard setting

Time: 15 minutes

1. Keep participants in the same groups as before.
2. Refer back to **Handout 14.1 Checklist for appraising a Quality Care Paper – Using Audit.**
2. Ask them to consider section 4 (results), section 5 (dissemination) and section 6 (validity and applicability of study results) of the checklist.
3. Bring the group back together to discuss these sections and any other outstanding issues.

Further reading can be found at the end of Chapter 15.

Chapter 15

Outcomes in healthcare

Introduction

How do we know whether or not an aspect of healthcare has net benefit? Is an intervention harmful? What health is gained, by an individual or by a population group, from a given procedure, be it an operation, a drug or a programme or care? Defining appropriate outcomes is an important part of measuring the impact of health services.

Aim

- to understand the rationale for monitoring outcomes in healthcare.

Objectives

For participants to know:

- what outcome indicators are
- how they are developed
- why they are used
- how to apply them to local practice.

Timing

Approximately 1 hour.

Materials

- *15.1, 15.2, 15.3, 15.4, 15.5, 15.6, 15.7, 15.8, 15.9, 15.10, 15.11, 15.12*
- Flipchart

This section consists of a slide-based presentation by the tutor or facilitator, followed by an exercise encouraging participants to think about measuring outcomes pertinent to their own area of work.

It fits well with the previous audit session.

Outcomes

A definition of an outcome is shown in ***Slide 15.1***.

Purpose of using outcomes

The purpose of identifying outcomes is to measure an effect (or lack of effect) in terms of benefit or harm of an intervention on a person's health. An outcome is classically stated in measurable objective terms even when considering issues such as pain or fear which are less easily defined. The components of an outcome should include identification of:

- the subject, eg pain
- the indicator, eg pain measurement tool
- acceptable level
- time frame.

Why use outcome indicators?

Outcome indicators can be used for a variety of purposes, as set out in ***Slide 15.2***.

Examples of uses of outcome indicators

Outcome indicators will be put to different uses depending on the agency or authority employing them, as shown in ***Slide 15.3***.

Divisions are shown for:

- public, patients and representing organisations
- trusts and primary care groups
- health authorities
- the NHS Executive.

An example: obstetrics

Obstetricians have led the way, as illustrated in ***Slide 15.4***.

Confidential inquiries

Their first confidential inquiry into maternal deaths was held in 1952. Other enquiries (see list on slide) started in the late 1980s/early 1990s.

The Clinical Outcomes Group

The Clinical Outcomes Group was set up in 1992, initially to offer advice on the strategic direction of audit to improve outcomes, but now has an expanded role looking at all aspects of the quality of clinical care.

Department of Health (DoH) support for outcomes work

The DoH is encouraging work in this area as it will underpin the drives to improve quality and effectiveness of healthcare. The Central Health Outcomes Unit is based at the London School of Hygiene and Tropical Medicine with a role to develop useful outcome indicators from routinely collected data.

Work on performance indicators is evolving, with the new National Performance Framework being consulted on in 1998 and launched in 1999. This is discussed further later in the presentation.

Direct and indirect measurement

Health improvement outcomes may be directly or indirectly measured as depicted in ***Slide 15.5*** and described below.

Direct measures

Direct measurement uses either national or local data that is either routinely or specially collected. Direct measurement is not always possible, owing either to the long timescale necessary to demonstrate an improvement in health status or the small numbers involved locally.

Process measures can be used as a proxy for health status measures where there is good evidence of the effectiveness of an intervention. Examples include the time of administration of thrombolysis in acute myocardial infarction and the administration of antenatal steroids to women in preterm labour.

Indirect measures

Processes of care may be measured by audit against evidence based standards in guidelines or by analysis of variance from care pathways.

Sources of information

Slide 15.6 sets out some examples of sources of information that may be used to look at some processes as a proxy for health outcome. Linkage between different local databases and administration systems allow for more refined analyses of data. PACT (Prescribing And Cost Data) data is about GP prescribing.

Use of outcome studies to investigate trends and activities

Outcomes studies can be used to investigate different trends and activities. ***Slide 15.7*** lists some designs.

Clinical indicators

Hopkins and Costain (1990), from the Royal College of Physicians, have a working definition of clinical indicators shown in ***Slide 15.8 – Criteria for clinical indicators***.

The six attributes are taken from the Department of Health's consultation document on the National Performance Framework of which the main aims are given in ***Slide 15.9***.

National targets

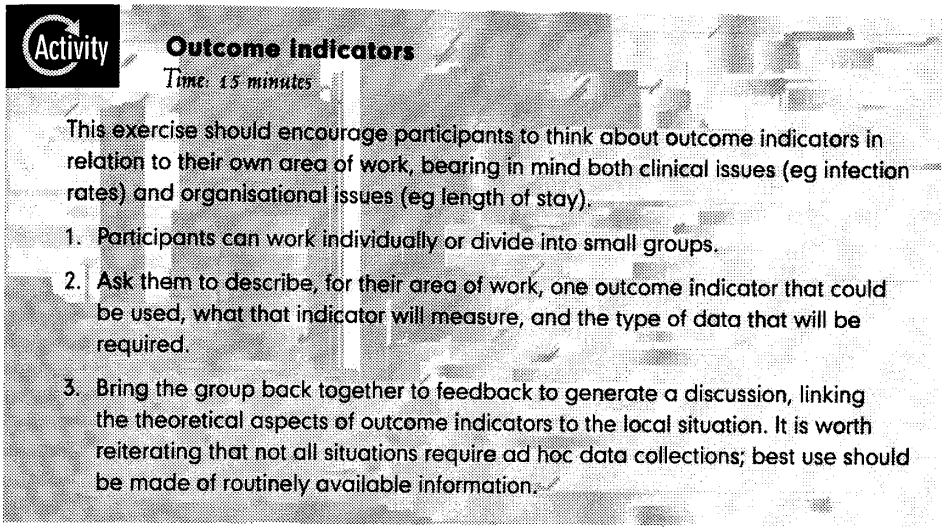
Some examples of national targets from the White Paper, *Saving Lives: Our Healthier Nation* (1999) are shown in ***Slide 15.10***. All health sectors (and other departments) are required to work towards them.

Health outcomes of NHS care

Some single and composite indicators that have been selected to illustrate the health outcomes of NHS care, one of the six areas of the National Performance Framework, are shown in ***Slide 15.11***.

Outcome indicators and the National Performance Framework

Breast cancer is used in ***Slide 15.12*** as an illustration of how outcome indicators can fit into the National Performance Framework.



Further reading

Closs, S. J. & Cheater, F. M. (1996) Audit or research – what is the difference? *Journal of Clinical Nursing* **5** 249–256.

Gray, J. A. M. (1997) *Evidence-Based Health Care*. New York: Churchill Livingstone.

Hopkins, A. & Costain, D. (Eds) (1990) *Measuring the Outcomes of Medical Care*. London: Royal College of Physicians.

Hopkins, A. (1990) *Measuring the Quality of Medical Care*. Royal College of Physicians. London.

Long, N. M. & Marek, K. D. (1990) The classification of patient outcomes. *Journal of Professional Nursing* **6** (3) 158–163.

Robinson, S. (1996) Audit in the therapy professions: some constraints on progress. *Quality in Health Care* **5** 206–214.

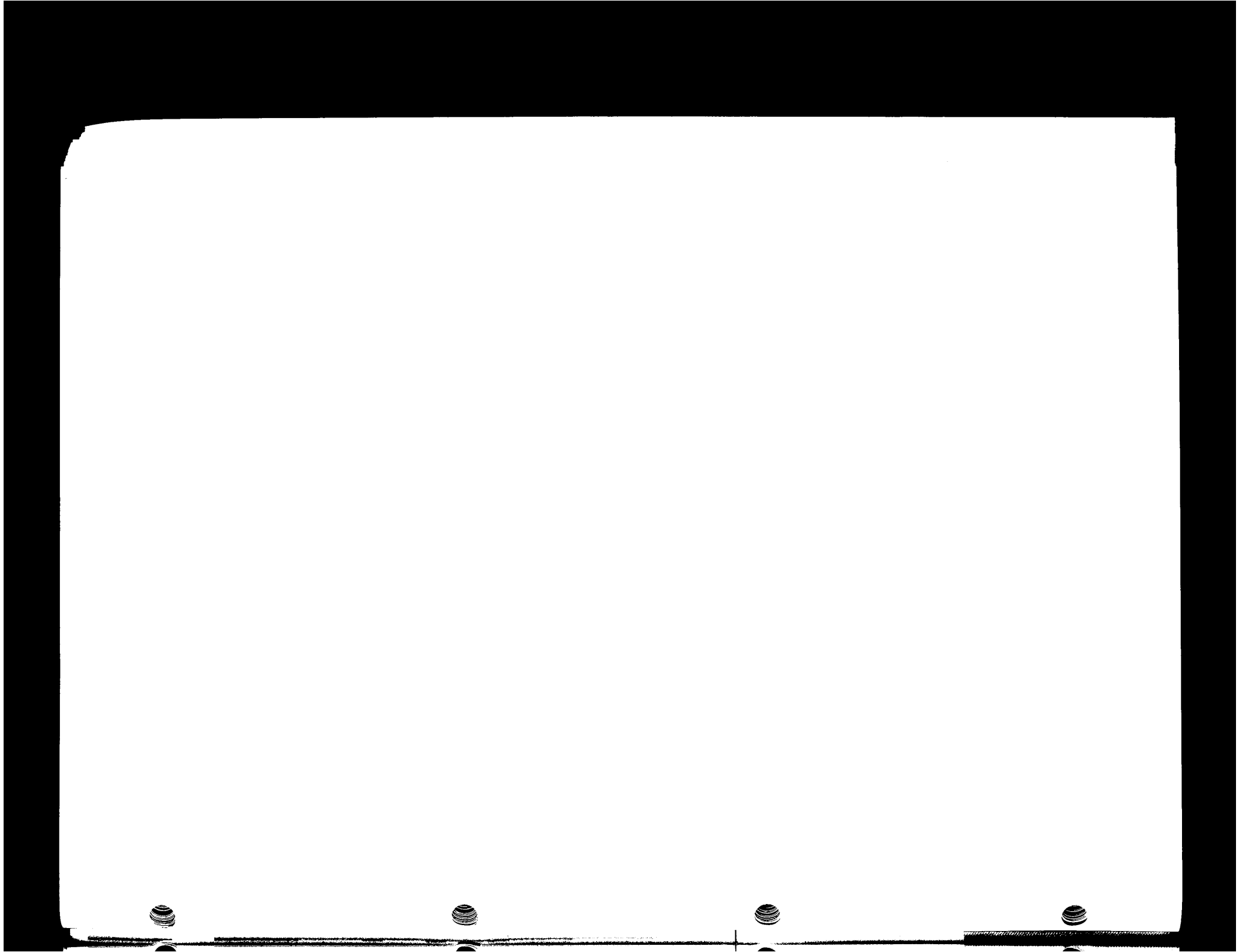
Ruddock, R. (1981) Evaluation: a consideration of the principles and methods. *Manchester Monographs* **18**.

Scally, G. & Donaldson, L. (1998) Clinical governance and the drive for quality improvement in the New NHS. *British Medical Journal* **317** 61–65.

Tierney, A., Closs, J., Atkinson, I., Anderson, J., Murphy-Black, T. & Macmillan, M. (1988) On measurement and nursing research. *Nursing Times* **84** (12) 55–58.

Walshe, K. & Coles, J. (1993) *Evaluating Audit – Developing a framework*, CASPE Research.

WHO (1993) *The Principles of Quality Assurance*. Copenhagen: WHO.



Part 4

Making change happen

Handout Masters

OHP Masters

Chapter 16

Project management

Introduction

While it is relatively easy to learn the skills that are required in order to make sense of research data and other sources of knowledge, making use of that knowledge in the practice setting is complex and difficult. Good project management can help reduce resistance to change (see **Chapter 17**). That there will be some resistance is almost inevitable, a factor which has been acknowledged widely for many years. Hence careful project management is an essential prerequisite to success in developing evidence based practice. This chapter is a critical component to help achieve that end.

It is helpful, but not essential, if participants come to this session with an identified project they are working on, or want to work on.

Aim

- to help participants gain insight into a way of managing project work in order to increase assurance of successful implementation.

Objectives

For participants to know:

- how to define and plan project work
- who to involve in the process
- how to identify factors which may hinder implementation
- how to identify strategies which will enhance progress.

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Timing

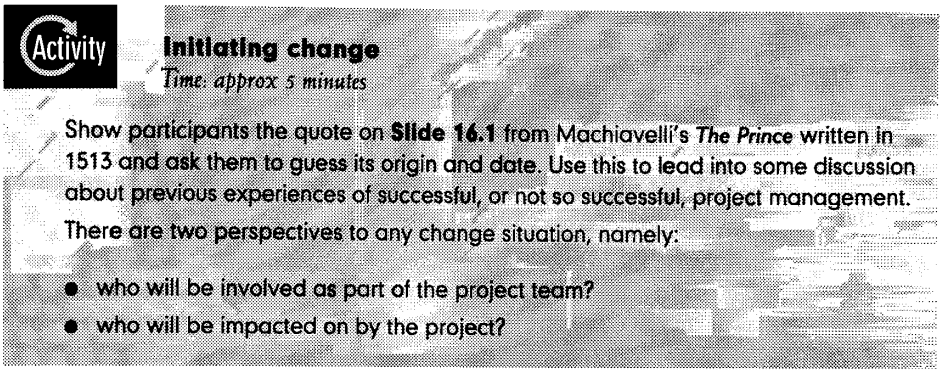
Approximately 45 minutes.

Materials

- *Slides 16.1, 16.2, 16.3*
- *Handout 16.1* (enough copies for all participants)
- Flipchart

This session is a good opportunity to help people to gain insight into the importance of putting time and energy into project management. ***Handout 16.1*** summarises the main points and can be distributed at the beginning or the end of the session.

Project management



The need for a team

There is a much greater likelihood of success if projects are carried out by teams rather than a single individual. For many projects it helps to work in a multi-professional team or project group since most changes affect more than one occupational group (see *Chapter 11*).

Early involvement not only ensures that differing views are taken into account from the outset, but also that the proposed change can be championed in different arenas by different group members.

Experience suggests that it may be easier to ask people to identify their interests at the outset of any programme linked to the implementation of evidence based practice and, wherever possible, to form a group to work together and provide support in taking action forward.

Those beyond the team

There is also a second group of people, often referred to as stakeholders, who may not be part of the project team, but who need to know what is happening. The team will need to:

- identify potential knock-on effects of the project on stakeholders
- identify stakeholders' needs
- develop strategies to meet those needs.

Team members and stakeholders

Time: 5 minutes

Ask participants to identify:

- who they might like to recruit to their project groups as active participants
- who else might be impacted by their proposed work.

Steps in project management

Project management can classically be broken down into six key areas, see ***Slide 16.2***.

They are: the mission, action plan, resources, motivation, leadership and teamwork, progress.

Each of these issues has been outlined in a little more detail below and may be taken as a discussion point for the group.

1. The mission

It is critical in project management that those concerned can clearly define:

- what is being proposed and why
- why the work is important
- what it is hoped the project will achieve.

The 'what and why' of a proposal can be found in the use of evidence in practice and is critical to the development of clinical governance. This emphasises:

- a professional obligation to account for practice
- the sound use of resources.

Stating the outcomes or results which are anticipated at the outset of project work will also give a marker against which success can be judged.

Making a case

Time: 5 minutes

This activity should be carried out by each participant, or where possible, an existing project group.

Having agreed on a broad area of action ask each participant/project group to decide how they would make a case to different people on each of the issues in **Slide 16.3**.

(You may prefer to complete this chapter and give people more time at the end of the session to complete this and other activities.)

It may be worth reminding participants that people from different occupational groups do not always use terms, or see priorities, in the same way. This needs to be taken into account in considering how clearly the proposal will be understood and valued by others.

2. Action plans

Placing a time frame on project work gives everyone concerned some indication of what will happen when. Nebulous timings (like soon!) or no timings at all can lead to a confused understanding within the team, with each member interpreting the time when tasks should be completed on an individual basis. A suggested framework against which times may be placed would be:

- frame answerable questions by...
- develop search strategy by...
- find and appraise evidence by...
- consider different methods for achieving change, including the means by which achievement can be assessed by...
- develop a strategy for implementation by...
- implementation of evidence into practice by...

It is important to remind participants that the need for change should be assessed before launching on a major project plan. Gathering baseline data is a critical part of this process and, if the project goes ahead, this data is essential for project evaluation.

Most people are far too ambitious with both the size of their projects and how long it will take. A word of caution at this point may be useful as they will need to return to this framework when developing their own project plans.

3. Resources

How large a project can be and how quickly it can be done will partly depend on the resources available.

For example if the project is being undertaken with dedicated time it may be possible to move more quickly than if it is being subsumed into an already overloaded work schedule.

Identifying resources

Time: 5 minutes

Ask the group to quick-think what local or national resources they may have available to help them in developing their projects, remembering that involvement and commitment of all concerned is likely to be helpful as a strategy in its own right.

Use the ideas outlined below as a prompt for this activity.

Resource issues	
Workforce	Who is available to help?
Skills	What is the range of skills needed for both assessing the evidence and introducing change to practice?
Technology	What technology is available to help in accessing data?
Money	Are there any positive or negative cost implications related to the proposed change?

4. Motivation

A will to succeed, by both the project team and other colleagues, can have a crucial influence on the way in which a project proceeds. Identifying who the key supporters are and who may need some persuasion to come on board can help to maintain motivation.

Activity

Securing support

Time: 10 minutes

(This activity may alternatively be undertaken at the end of the session.)

This activity is ideally completed in project teams, but can also be undertaken by individual group members.

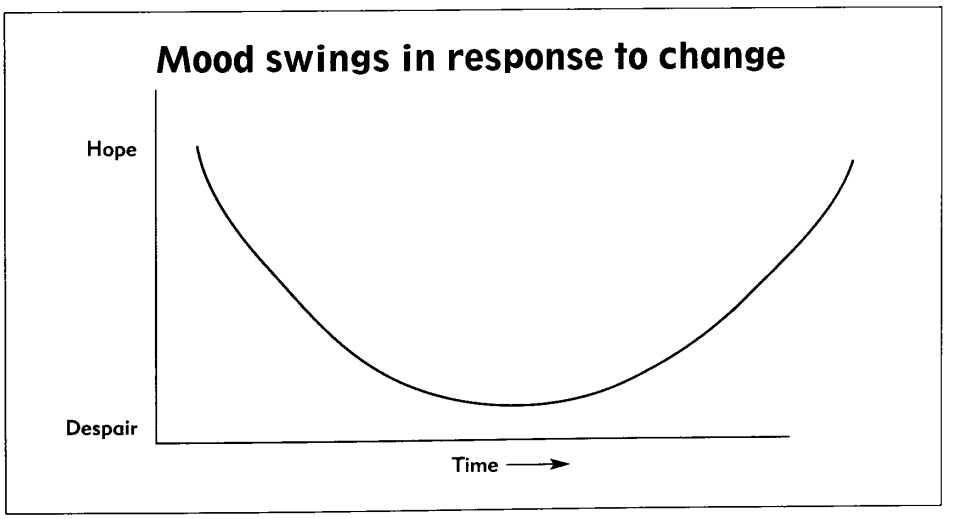
At the beginning of this section participants were asked to identify who their project might impact on.

Ask participants to return to this list and reconsider the range of people who may be concerned with their work, prompted by the following questions:

- who are the stakeholders in this project?
- how will you secure access and support from the stakeholders?
- who may be the main supporters and why?
- who may you have to persuade and how will you do this?

Tip

Bear in mind that people's moods do change over time. A classic mood curve (below) has been described in relation to change. You may choose to draw this for participants on a flipchart in this session or when you are dealing with change management in *Chapter 17*.



5. Leadership and team work

Team work, linked to skilled leadership, is the key to success in project work. There has been a tradition in healthcare that it is the most senior person in the project team who will undertake the leadership role. In the case of a project leader, there is no reason why this tradition should be adhered to. It may be more appropriate to vest the leadership in the person who is closest to the development of the work, supported by colleagues in a range of different positions in the organisation.

Project leader's responsibilities

Time: 5 minutes

In order to identify who the project leader should be you might find it helpful to consider the responsibilities such a person would have. Ask the group to say what they think the responsibilities would be and note the suggestions on a flipchart. Ensure those listed below are included.

Responsibilities of the project leader

- managing the project environment
- managing human and technical resources
- delegating responsibility for each specific task
- minimising opposition
- stating and re-stating the project mission to everyone involved
- maintaining motivation

Project leader's role

Time: 5 minutes

The project leader also has an important role to play in helping to build and maintain good working relations within the team. Consideration of how the following issues would be handled can be used as a useful prompt for discussion. Ask the group to suggest ways of handling the issues and note the suggestions on a flipchart.

Suggestions

- building relations between team members
- ensuring that individual members take responsibility for allocated tasks with agreed outcomes and deadlines
- ensuring that all team members have a role to play
- building relations with other teams

This may be the time to stress the importance of building on other people's work. For example, close links with the audit team may help to short circuit some aspects of project work within an EBP programme.

6. Progress

Progress meetings need to be built into the project plan from the outset. It is helpful to agree their frequency, dates and times.

Project meetings

Time: 5 minutes

Ask the group to quick-think to generate a list of all the reasons to have progress/project meetings. Note their ideas on a flipchart, ensuring the following are included:

- keep up the momentum of change
- identify any difficulties at an early stage
- allow for rescheduling if needs be
- act as a powerful motivator when different phases are completed
- review planned against actual task achievements
- if targets are not being met, to explore why this is so eg were original plans too ambitious
- agree what remedial action should be taken if necessary
- revise project plan to the end of the programme
- celebrate achievements to date.

Progress meetings can also be used to:

- critically assess the rigour of the evidence
- draw tentative conclusions
- discuss implications for the scope of the project
- decide whether further work is needed.

While project management may seem peripheral to evidence based practice it is, at the end of the day, a critical part of the process required to bring about real change. It is useful to give participants ample time to talk this issue through.

You may also find it helpful to review this session in conjunction with *Chapter 17 Change management*, in order to develop a programme which is sensitive to the local needs of the people with whom you are working.

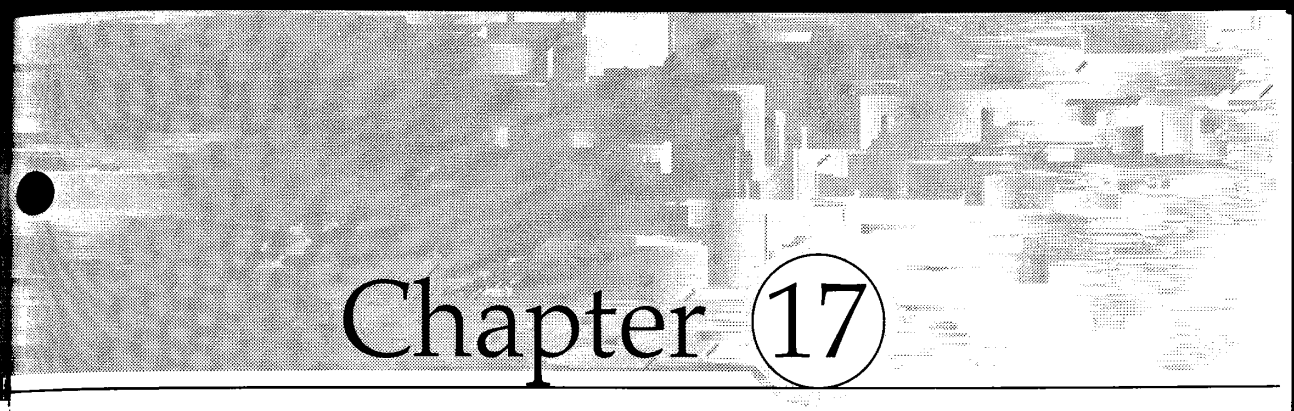
A final word

Most people are over ambitious in their expectations of both themselves and others, especially where managing change is concerned. As a final note you may wish to share the following note of caution with participants.

Small is beautiful

Remember – most people try to tackle too much too quickly

Further reading for this session is given at the end of Chapter 17 Change management.



Chapter 17

Change management

Handout Masters

OHP Masters

Introduction

That change is part of our everyday lives is widely accepted by people today. It is not just the explosion of new knowledge which makes this so, but also the speed with which other changes are occurring. Thus an understanding of what helps or hinders the successful management of change is an essential component of the development of evidence based practice. All these changes require some sort of response. That this is acknowledged and recognised as challenging is evident in the Department of Health publication *A First Class Service: Quality, the New NHS* (1998.

Aim

- to introduce participants to the principles of change management, building on both theory and personal experience.

Objectives

For participants to know:

- the relevance of the context in which change takes place
- common reactions to change and the rationale behind these reactions
- ways in which resistance may be manifested
- how to assess the change situation using a forcefield analysis
- principles of managing change.

Timing

Approximately 1 hour.

Materials

- *Slides 17.1, 17.2, 17.3, 17.4*
- *Handouts 17.1, 17.2* (enough copies for all participants)
- Flipchart

The principles of change management

The aim of this session is to introduce participants to the principles of change management, building on both theory and personal experience.

You may want to use the quotes below (which are in ***Handout 17.1***) as a starting point for conversation or as examples from the literature which will substantiate your introduction.

Of change

'Predictability...is a thing of the past. Nothing can be taken for granted any more.'
Peters & Waterman, 1982

– of a potential threat

'The re-defining of boundaries across and between the professions and between professions and other health care workers, combined with more flexible patterns of employment may be interpreted as threatening. They need not be...what must underpin any innovation...is a sound knowledge base, accountable practice and peer review and support.'
Department of Health, 1995

Experience of change
Time: 5 minutes

1. Ask participants to quick-think the range of issues which are impacting on their day-to-day working lives as time moves on, such as changes in working relations, technology etc.
2. Record their responses on a flipchart.

It is useful to have a prepared list summarising some of the issues which affect day-to-day clinical practice and to compare your ideas with those of the group. Those you may wish to use as a focus for further discussion, if not thrown up by the group, are:

- **technology**
- **methods of communication**
- **new drugs**
- **transport and pollution**
- **junior doctors' hours**
- **changing shape of healthcare**
- **new knowledge**
- **changing tastes of the population.**

The issue is that, like it or not, we must learn to live with change, which can be seen as either a positive or a negative force. As Tom Peters has said:

> *'Violent and accelerating change, now commonplace, will become the grist (corn) of the opportunistic winners' mill. The losers will view such confusion as a "problem" to be "dealt" with.'*
> **Peters, 1982**

It has been suggested that individuals 'seek to live in a state of equilibrium'
Schein, 1969

It is important for all of us that we can match our current behaviour with what we believe to be true. Hence the introduction of new knowledge (eg that from the use of evidence based practice) may well disturb our equilibrium and create a feeling of dissonance. It is this dissonance which can cause some people to feel uncomfortable and defensive.

Similarly organisations seek an equilibrium and:

'...work as a result of a dynamic balance of forces working in opposite directions with equal pull.'
Lewin, 1951

Knock-on effects of changes

If any one part of an organisation shifts then there will be a knock-on effect throughout the whole structure and a new balance will need to be found.

A simple example occurs when changes are made to meal times in order to offer more choice to patients. This may suit patients and nurses well, but consideration would also have to be given to housekeeping and catering teams, medical rounds, budgetary implications and so on. At the end of the day there is a need to find a balance which would accommodate the range of needs. For example, public transport may not allow catering staff to work more flexible hours so alternative solutions would need to be explored which take this restriction into account.

Experience of managing change

Time: 10 minutes

1. Ask participants to break into small groups of two or three.
2. Ask them to identify any experience they have of managing change, maybe using a critical incident (see **Chapter 6**). Some group members may want to share their personal responses. Others may wish to look at the wider impact which the change had on others and to raise questions about whether full consideration had been given to the impact of the change on the whole system.
3. Encourage them to identify any problems they have become aware of in the light of experience, in order that such issues could be predicted and managed in the future, eg failed to see 'knock-on' effect for others, underestimated time, lost impetus.

Most people have some experience of change and can recall how they felt, especially when change was imposed on them. This can be a useful starting point which helps participants to recognise that both they, and the people they will be working with, will already have a repertoire of skills which can help them to understand and hence manage future change.

Recognising and understanding resistance

While some people are excited by the thought of change, it is far more common to feel a degree of anxiety in a situation which requires change. (See the DoH quote on page 142 and in *Handout 17.1*.)

The best way to avoid or overcome resistance is to be able to recognise it in its early stages. As a starting point it is useful to have some insight into why such resistance may occur in order to be able to help people to overcome their resistant behaviour.

Activity

Why and how people resist change

Time: 5–10 minutes

1. Ask the whole group to quick-think ideas about why people may be reluctant to change, drawing on their personal experience and their theoretical knowledge. Note the responses on a flipchart.
2. This may be followed with a second quick-think session to identify how resistance may be manifested.

Suggest participants consider why people are reluctant under the four headings:

- cultural resistance
- social resistance
- organisational resistance
- psychological resistance.

Note the responses on a flipchart.

Ensure that the following are mentioned:

Cultural resistance	values and traditions threatened
Social resistance	relationships threatened, eg new teams different work hours tribalism
Organisational resistance	lack of time status threatened new reward systems
Psychological resistance	fear of the unknown change perceived as not beneficial threat to value of previous behaviour

When discussing how change is resisted (behaviour) the following are examples

- lip service
- aggression
- sabotage
- sub group cults
- absenteeism or increased sickness
- lethargy

Time is well spent at this stage in talking with participants about:

- **how common they think such behaviours may be**
- **stressing that to be forewarned is to be forearmed.**

Increasing their understanding of classic 'change behaviour' will place them in a strong position to minimise resistance and build on strengths.

Anticipating responses

In order to plan change effectively it is useful to consider what is going on around the 'change situation' which may either enhance or inhibit the way in which it proceeds. One way of doing this is to use a technique known as force field analysis – see *Handout 17.2*.

Force field analysis

'A technique for seeking consensus about the critical factors related to a specific issue.'

There are four basic steps to force field analysis.

Step 1: List driving and restraining forces – all the factors which may act as either driving or restraining forces to the change.

Some of the common factors which people may list include those below. As you can see, many of these issues can be either driving or restraining forces.

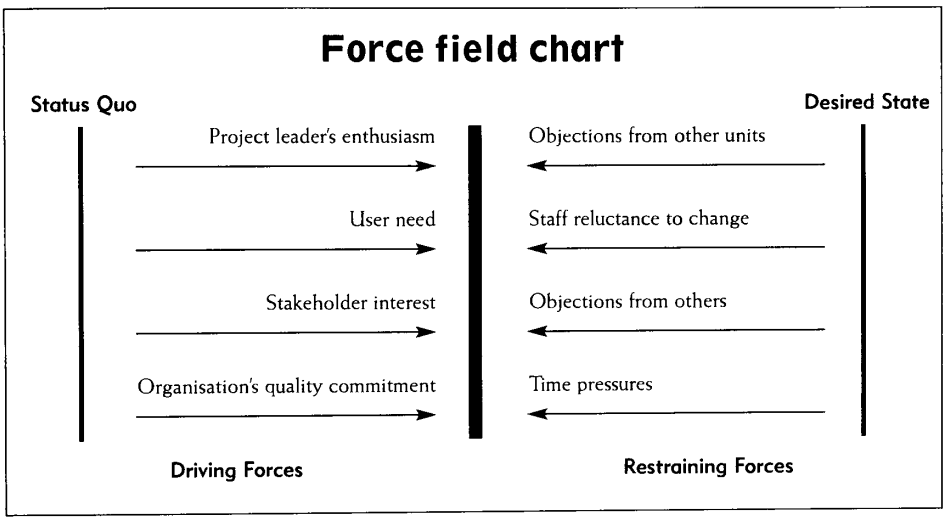
- management support
- resources
- organisational support
- organisational culture
- interprofessional relations
- purchaser support
- user expectations
- organisational, professional and government agendas
- pressure of time

Step 2: Categorise the list – split the list into the following three categories:

- personal factors
- team factors
- organisational factors

Step 3: Drawing the force field chart

Driving forces are placed on one side of the chart and restraining forces on the other. The strength of the force is indicated by the length of the arrow, with stronger forces indicated by longer arrows as in this example:



Step 4: Review the chart

In the final stage, each side of the chart is reviewed in turn, asking the questions:

Driving forces

- which forces can be strengthened?
- how can this be done?

Restraining forces

- which forces can we do nothing about? Ignore these factors
- which forces can we do something to undermine or weaken?
- how can this be done?

It is worth noting that it is better to reduce restraining forces than to try to strengthen driving forces – it is the restrictions that can stop changes happening.

Handout Masters

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This activity is for completion outside the workshop session

Time: 30 minutes

1. Once participants have decided on the area of work they would like to focus on as part of their move to evidence based practice ask them to spend time, preferably in small project groups (see **Chapters 11** and **16, Local Implementation and Project Management**), drawing up a forcefield analysis related to their chosen area of interest.
2. They should then draw up an action plan to counter restraining forces or strengthen driving forces.

Getting people on board

Three major approaches have been described for getting people on board. These are listed in *Handout 17.2* and summarised below.

Methods of getting people on board

Rational-empirical

The rational-empirical view of change is based on the premise that all action can be guided by reason. Thus, if there is a research base for a particular practice, then it will be used because that is the logical thing to do. In this case, then, power comes from possessing knowledge.

Power-coercive

In the power-coercive model, power is vested in status and control. Essentially, there is an assumption that people with less power will comply with the will of those with greater power.

Normative re-educative

The normative re-educative model contrasts these two 'top down' views and is probably the one which would be most attractive to healthcare professionals. Essentially it works on the premise of local involvement, shared exploration of need and involvement in decision-making, which is reflected in the move to patient-centred care and partnerships in decision-making.

Choosing between the approaches

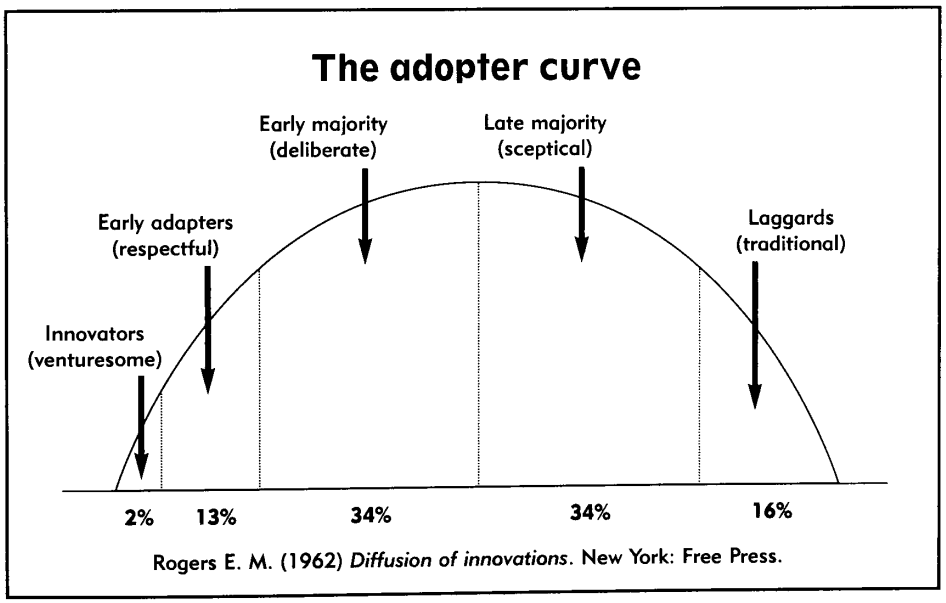
It has to be said that no one approach works all of the time – even if one feels ideologically right for you. If one approach always worked, there would not be a smoker

left in the world and everyone would clean their teeth after meals. But human nature is just not like that. Hence in reality, and with a full awareness that these things take time and energy, systematic plans are needed to minimise resistance and maximise strengths.

Planning change

Planning change involves the same steps as managing any other activity, as outlined in ***Slide 17.1 – Planning change***.

It may also be worth remembering that it is unlikely that all team members will be as eager to modify their ways as those who have instigated the change. A classic curve has been described which gives some indication of the point at which different group members may change. ***Slide 17.2*** shows this.



Rogers E. M. (1962) *Diffusion of innovations*. New York: Free Press.

Principles of change management

Finally you may wish to introduce group members to the work of Berwick who has developed five guiding principles in relation to change. See ***Slide 17.3***. He suggests that, as far as modern healthcare is concerned:

'...never before has common sense been so uncommon.'

The principles which he suggests should guide change are:

'Focus on integrating experiences not just structures'

The argument here is that there is little point in changing structures unless this has a real impact on the experiences of those concerned. In this context some may question, for example, the initial way in which some organisations responded to waiting times in accident and emergency departments which had little impact on clinical care.

'Learn to use measurement for improvement – not measurement for judgement'

An example which you could draw on here is the amount of effort put into audit (or measuring) in relation to the amount of support given to help people to respond the results of audit. Some would suggest that the balance is inappropriate.

'Develop better ways to learn from each other, not just to discover best practice'

Berwick's principle here relates to the manner in which evidence is used, always bearing in mind that attention must be paid to the local contextual needs. In other words local wisdom and learning should not be ignored but built on alongside the scientific evidence (see ***Chapter 4***).

'Reduce total costs, not just local costs'

The discussion on these principles could be brought around to the manner in which healthcare has become compartmentalised, with concern for local issues without acknowledgement of the wider implications. Thus a cost saving at one end may shift rather than reduce cost. While these issues are notoriously difficult to evaluate it is important that they are considered.

'Compete against disease, not against each other'

Finally Berwick raises the thorny issue of tribalism and concern for territory and turf among health professionals. Tribalism has already been mentioned as a reason why people will resist change, but it is a real concern in the world of practice. Listening and learning from each other, patient-centred care and an awareness of the wider aspects of managing health and illness all fit in here.

Finally, you may wish to share with the group the sentiments on ***Slide 17.4***.

Of people who have gained emancipation:

'...they let go of their present conceptions of how to solve problems ... once they let go they have the capacity to come up with brave solutions that integrate all the information.'

(Carr & Kemmis, 1987)

References

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Appendix

Teaching through workshops

Handout Masters

OHP Masters

The presenter's role

- to identify expectations
- to present information
- to involve participants
- to monitor progress
- to handle problems
- to ensure feedback

Identifying expectations

When?

- at the start of the workshop
- during the workshop

It is important to match the workshop content and approach to participants' needs and expectations. Even when working from a published, field-tested package, there is no guarantee that the package will exactly match your participants' needs. If you fail to take account of the needs you may fail to gain participants' confidence and so prevent the learning process from starting.

How?

There are many methods which you can use to establish the participants' needs and expectations. These include the following.

Quick-think

You can ask participants to produce as many ideas as they are able to on:

- what I want from this workshop
- what I do not want from this workshop.

This can be done at the outset, and during the workshop.

Prioritising

Similar to quick-thinking but you ask participants to produce, say, three things they most want covered and three things they least want covered.

Sentence completion

Here you give participants a very specific prompt in the form of an incomplete sentence, eg:

I feel that we should spend more time on...

I think we have had enough of...

I would get more out of this workshop if....

Groups or individuals?

You will need to decide whether you wish to elicit the needs of individuals, or of small groups, or of PHCTs. In the case of individuals, you probably need to make the process anonymous. This can be done by asking participants to put their points on Post-it notes and then to stick these on flipchart sheets around the room.

Presenting

Selecting

You will have to decide which parts of the package to present. Your decision depends on the needs of your participants and the time available.

Learning requires application and activity. Do not be tempted to extend your presentation at the expense of participant activity. You may feel that you have covered more but your participants will have learnt less.

Adapting

Once you have selected the parts of the package that you wish to use, you will need to adapt these to meet participants' needs. For example, you might skip some points that you know will not be acceptable to the group; you might add in other points that you know your group needs. More importantly, perhaps, you might add new buzz group activities if you find that your sessions are becoming too one-way.

Illustrating

Examples are generally more vivid than abstract material. There are examples in the package but feel free to add more. You can add from your own knowledge and experience. You can also get the participants to cite examples of their own.

Presenting rules

Successful presentation depends partly on content and partly on style. Good style will never overcome poor content but good content can be ruined by poor style. The following tips will help ensure that your presentation is effective:

- maintain eye contact with your audience at all times and make sure that contact is with the whole audience and not just those to one side or near the front
- do not look at the overhead screen – if you do, you have turned your back on your audience
- remember that the purpose of the overhead projector is to command attention; when you want the audience to look at you, switch off the projector
- avoid distracting mannerisms such as jangling keys or coins
- be positive; try to make clear, positive points
- be confident; if you are not, how can participants be?
- stand when you are presenting – it may be democratic to sit but you are not a participant, you are the leader.

Room layout

Decide on a layout which:

- enables all participants to see you
- enables all participants to see the overheads clearly – check this using one of your acetates before the session starts by sitting in various seats
- enables participants to see each other if possible
- is easily re-arranged by participants for buzz groups.

Involve participants

We learn very little by being told. Most of what we truly understand has been acquired through active use of that material. Activity is at the heart of learning. Here lies the challenge for presenters: how to make your participants participate.

There are a number of ways of making your presentations active. These include the following.

Types of activity

Questions

You can pose questions to check understanding, check pace, check level or ask for examples. Beware, though. If you ask 'Would anyone like to comment on...' or 'Is this about right for you...' you may well get a total silence. Questions posed like this tend to fail because: (a) they ask individuals to speak for the group. How can they? and (b) most people are embarrassed about admitting that they do not understand something or that the pace is wrong.

On the whole, direct questions are not useful in promoting activity.

As you get to know a group better, you can more easily use questions. For example, once you know each group, you can use that knowledge to shape questions into acceptable forms such as 'Peter, your unit tried a diet questionnaire. Would you like to tell us what sort of problems you had?'

Sentence completion

You can use this to: (a) provoke some interaction from an otherwise non-involved group or (b) to elicit some information that you genuinely need. You pose an incomplete sentence and ask for ways in which it might be completed. Examples include:

> Community diagnosis will be difficult for us because...
> We can integrate change management with other practice work by...

Voting

Voting can be useful to you in helping to establish the participants' needs and in shaping your presentation as you go along. Some votes can be by show of hands, others by asking participants to put a tick on a flipchart. We have used the flipchart method to get 40+ people to vote on 35 different options for an afternoon session. It took less than 5 minutes and produced a clear result.

Scoring

This is a more sophisticated version of voting. It can be used to establish, say, current practice or experience. For example, you could get participants to rank a list of reasons for attending this programme.

Asking for examples

Bearing in mind the caveats about direct questions, you can ask participants for examples from their own experience.

Procedural aspects

Once you have decided on the type of activity that you want, you need to decide on its procedural aspects.

First, you need to decide whether it is to be an individual or group activity. Generally speaking, you should choose an individual activity if:

- a group approach would fail to get the information you need
- participants would be inhibited or embarrassed by a group approach.

Where neither of these is the case, a group approach is probably best.

For both group and individual activities, you need to decide on how the results will be gathered and presented. Methods include the following.

Buzz groups

Buzz groups are half way between individual tasks and full group activities. A buzz group is an informal small group formed without participants leaving the presentation room. They are a very powerful way of bringing life and purpose to a presentation – especially if you pick the right question for them to work on.

Post-its

These can be completed anonymously and stuck onto flipchart sheets. Participants can be encouraged to walk around and look at all the offerings.

Straight questions

These have already been discussed.

Flipchart notes

Here you, or the participants, put the responses onto a flipchart sheet.

Mini presentations

One or more participants can come to the front and present the results of their activity.

Monitor progress

At all times, you need to be aware of how well your presentation and tasks are matching participants' needs and expectations.

Potential areas of mis-match

You might find that there is a mis-match because of:

- starting at too high or low a level
- using vocabulary and acronyms that are not familiar to your participants
- content which is not relevant to participants' situations (eg lots of rural examples when all the practices are inner city).

Potential problems which prevent learning

- Participants may have hostile or negative feelings about the workshop, eg if they have been directed to attend; learning will not take place unless these are addressed.
- If you have problem participants (discussed below) and fail to handle them, you may build up hostility in the rest of the participants; this will inhibit learning.
- Participants may be bored, uncomfortable, hungry or in some other way distracted from the session; you need to know this.

How to monitor progress

You can monitor progress directly and indirectly.

Indirect monitoring involves you drawing monitoring conclusions from activities and processes that are not overtly monitoring ones. You can do this through the following.

- By observing the directedness and responsiveness of the buzz groups. Are participants willing to work on the topic, or are they straying? Do they seem keen to work together?
- By generally observing the depth and quality of all the interactions. Are the interventions to the point? Do others listen and show signs of approval?
- By observing body language. Are people showing signs of attention and involvement? Or are they showing signs of withdrawal, hostility, defensiveness or just plain tiredness?

Problem people

You have a major responsibility for dealing with problem people. If you fail to handle them effectively, you may find the rest of the participants becoming quite hostile (overtly, or by withdrawing). Participants expect you to act to maintain the purpose of the group. You should not feel inhibited in taking any necessary action.

Problem types and possible actions

Dominators

These people hog discussion, ask all the questions and always have the last say. Once a dominator has made himself or herself known, you can deflect his/her questions and comments by saying things like:

'I think we ought to get some views from the rest of the group.'

'Let's see if that question is important to the rest of the group.'

If this does not work, you must take stronger measures – perhaps a word in private – but, if necessary, a formal refusal to take points from the person.

One-subject people

These are like dominators but with a one-track mind. Whatever the topic of the session, they manage to raise the same point again and again.

You can handle this by:

- pre-empting the person: 'I know that Mary would say...but'.
- ruling the topic off-limits: 'Let's talk about that without any mention of... which we now know so much about'.

The expert

The expert is genuine. He or she really does know more than all the rest of those present about a certain topic. The trouble is, he or she does not know when to stop contributing. One way of dealing with this is to formally give the expert a short slot on the programme.

The mouse

The mouse is no trouble to others but should be a worry for you. Mice, unless they participate, will not fully benefit from the workshop. You can help mice to participate by:

- putting in lots of small group work, eg buzz groups of just two
- finding something non-threatening for the mouse to talk about, eg part of his/her group's feedback.

The distracter

Distracters won't keep to the point. They bring their own agenda.

In the plenary sessions, you must be firm.

'It would be nice to go into that, but it is not something we can deal with in this session.'

If the topic is one which ought to be dealt with then your response must recognise this:

'We can't really go into that now. Would you raise it again in this afternoon session?'

The plain hostile

Generally these are people who have their own agenda. For example, they may have been directed to attend and are taking out their hostility to their superior on the group or on you.

You may be able to allow some letting off steam within the programme. For example, if the person's hostility arises from a deep scepticism about EBP, allowing the person to voice that scepticism may help lower the hostility.

On the whole, such people are worse in larger groups. Plenty of early small group work, honest discussion and feedback sessions will help reduce the problem.

Feedback

Your final role is to ensure that participants can feed back their thoughts, work and reactions to each other and that you get feedback from the group on your work.

Participants to participants

In the formal feedback sessions your role is as follows:

- to ensure strict time limits are kept to
- to make best use of feedback time, you can suggest that feedback overheads and flipcharts are taken as read
- in place of presenters reading out their material, ask them to pose some questions/ issues for the group so that the group interacts with the feedback
- if necessary, you could even stop the feedback and form buzz groups
- whatever happens, the feedback should be a mutual learning experience for all concerned. If it is not, think about how you can make it so.

Group to you: getting feedback

You have already met a variety of methods of getting responses from participants. These can be used to get feedback on how the workshop is going. As ever, your first decision is:

- do I want individual views, task group views or buzz group views?

To get these views, you can use:

- sentence completion
- best three things/worst three things
- most useful/least useful lists
- mastered/still need help with lists.

Further reading

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Cascading Evidence into Practice

Cascading Evidence into Practice Cascading Evidence into Practice Cascading Evidence into Practice

Handout 1.1

Main components of clinical governance

Clinical governance outlines clear lines of responsibility and accountability for the overall quality of care through:

- the NHS Chief Executive who carries ultimate responsibility for assuring the quality of services provided by the trust
- a designated senior clinician responsible for ensuring that systems for clinical governance are in place and for monitoring their continued effectiveness
- formal arrangements for NHS Trust boards to discharge their responsibilities for clinical quality, perhaps through a clinical governance committee
- regular reports to NHS Trust boards on the quality of clinical care being given the same importance as monthly financial reports
- an annual report on clinical governance.

A comprehensive programme of quality improvement activities which includes:

- full participation by all hospital doctors in audit programmes, including specialty and subspecialty national external audit programmes endorsed by the Commission for Health Improvement
- full participation in current National Confidential Inquiries
- evidence based practice being supported and applied routinely in everyday practice
- ensuring that the clinical standards of National Service Frameworks and NICE recommendations are implemented
- workforce planning and development (ie recruitment and retention of appropriately trained workforce) is fully integrated within the NHS trust's service planning
- continuing professional development programmes in place and supported locally to meet the development needs of individual health professionals and the service needs of the organisation

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- appropriate safeguards to govern access to and storage of confidential patient information
- effective monitoring of clinical care with high quality systems for clinical record keeping and the collection of relevant information
- processes for assuring the quality of clinical care are in place and integrated with the organisation's quality programme.

Clear policies aimed at managing risks, such as:

- control assurance, which promotes self assessment to identify and manage risks
- clinical risk is systematically assessed with programmes in place to reduce risk.

Procedures for all professional groups to identify and remedy poor performance, including:

- critical incidence reporting ensures that adverse events are identified, openly investigated, lessons are learned and promptly applied
- complaints procedures are accessible to patients and their family and fair to staff. Lessons are learned and recurrences of similar problems avoided
- professional performance procedures – which take effect at an early stage before patients are harmed, and which help individuals to improve their performance – are in place and understood by all staff
- staff are supported in their duty to report concerns about colleagues' professional conduct and performance, with clear statements from the board on what is expected of all staff. Clear procedures for reporting concerns so that early action can be taken to support the individual to remedy the situation.

Handout 2.1

Formulating answerable questions: exercise

For a given clinical scenario, frame a precise question of interest to:

- the patient
- the clinician.

Four steps to be followed:

- describe the group of patients with similar characteristics
- decide on the interventions to be used
- identify the main comparisons
- define the outcomes of interest.

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Handout 2.2

Antenatal screening scenario

Caroline Smith, aged 25 and previously fit and well, booked for shared antenatal care with her GP at 8 weeks into her first pregnancy. She was surprised when he told her to attend the hospital for a scan at 18 weeks, he would see her again at 28 weeks and 36 weeks and that she would see the hospital consultant at 40 weeks of pregnancy. Her best friend Mandy had enjoyed her fortnightly visits to the midwives' clinic throughout her pregnancy. Caroline was concerned that she was being offered so little antenatal care.

Caroline Smith

P 25 year old healthy primigravida (first pregnancy)

I Reduced antenatal schedule

C Traditional pattern of care

O Healthy mother and baby; patient satisfaction

Question: does a reduced antenatal schedule for a healthy 25-year-old primigravida rather than the fortnightly visits to a midwife-led clinic impact on a) a healthy mother and baby b) parent satisfaction.

(Other questions are possible for this scenario.)

Handout 2.3

Hernia repair scenario

Tony King is a 56-year-old non-smoker. His inguinal hernia has, in the past month, started to hurt. Mr Fixit, a general surgeon, advised him to have a hernia repair: 'It will be keyhole surgery and you will be home the same day.' But Mr King was worried – his father had had bilateral recurrent inguinal hernias and had ended up wearing a truss.

Tony King

P 56-year-old male with inguinal hernia

I Day case laparoscopic hernia repair

C Open repair (day case or inpatient stay)

O Hernia recurrence rate; post operative morbidity; patient satisfaction

Question: is the recurrence rate for inguinal hernia greater for male patients aged between 40 and 60 when undergoing day case laparoscopic repair rather than open repair?

(Other questions are possible for this scenario.)

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Handout 2.4

Asthma scenario

Stephen Webb is a 38-year-old man who was discharged from hospital last week following a severe asthma attack. He had asthma as a child, but prior to this admission had not experienced any symptoms at all since the age of 15. His medication now includes a ventolin inhaler for acute shortness of breath and becotide, an inhaled steroid. Stephen is an accomplished long-distance runner and questions the consultant at his follow-up out-patient appointment about concerns over his fitness to compete in the London marathon.

Stephen Webb

P 38-year-old male with recurrent asthma

I Current medication with ventolin and becotide

C Other treatment regimes

O Optimal symptomatic control; prevention of relapse

Question: does the use of a combined ventolin and becotide inhaler for fit, athletic adults, provide optimal symptom control when compared with other treatment regimes?

(Other questions are possible for this scenario.)

Handout 2.5

Leg ulcer scenario

Sheila Jones is a 74-year-old woman who developed a venous leg ulcer in July having knocked her lower leg on a coffee table. She visited her GP, who arranged for a district nurse to visit once a week to apply a triple layer of bandages. As this happened during a hot summer, Mrs Jones has found the bandaging very hot and uncomfortable. She remembered that a friend of hers had had a similar problem, and she was treated with a small dry dressing placed on the ulcer. Mrs Jones' main concern is that the ulcer will be healed before her holiday at Christmas. However, if there was little difference between the effectiveness of the dressings, she would prefer the smaller, cooler dressing.

Sheila Jones

P 74-year-old woman with a venous leg ulcer

I Triple bandaging

C Dry dressing, alternative dressings

O Healing of wound and comfort of dressing

Question : what is the healing rate of leg ulcers in an older population (70+) using the triple bandage regime, compared with the use of dry dressings?

(Other questions are possible for this scenario.)

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Handout 3.1

Some database sources

Specialist review sources

- Cochrane Database of Systematic Reviews (CDSR)
- Cochrane Controlled Trials Register (CCTR)
- Database of Abstracts of Reviews of Effectiveness (DARE)
- NHA Economic Evaluation Database

General healthcare sources

- Medline
- Cinahl
- Embase
- HealthSTAR
- SCISEARCH
- DH-Data

Some subject-specific database sources

- CancerLit
- PsychLit
- AIDSLine
- Toxline

Yet more sources of written information...

- Evidence Based Medicine
- Evidence Based Nursing
- ACP Journal Club
- Bandolier – available on the Web
- Effective Healthcare Bulletins
- Effectiveness Matters
- AHCPR guidelines – available only on the Web
- Best evidence

And yet more sources on how to find the evidence...

- Andrew Booth, *Netting the Evidence*, a ScHARR introduction to evidence based practice on the internet.
  www.shef.ac.uk/uni/academic/R–Z/scharr/ir/netting.html
- ScHARR Information Resources.
  www.shef.ac.uk/uni/academic/R–Z/scharr/ir/scebm.html

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Handout 4.1

Types of knowledge

Empirical

Empirical knowledge is that which has been gained by testing theories. This is the approach most frequently used by scientists. The knowledge gained acts as the background to our judgement.

In discussing what you had for dinner, the empirical approach could be used to help people to understand the nutritional value of different foods.

Ethical

Knowledge of ethics is used in making moral decisions. It has been argued that there is a degree of morality in every decision we make (Downie & Calman, 1987). For example:

- when allocating resources
- when deciding the ethical acceptability of treatment regimes
- in major questions arising from the genome project
- in the debate about euthanasia.

In discussing what you had for dinner, there may have been some members whose diet is influenced by their religion or their values.

Aesthetic

Aesthetic knowledge refers to the artistry where meanings get changed into actions. It is exemplified by the expert practitioner who recognises the small but subtle changes in a patient before they have been observed by others, which may cause the practitioner to deviate from the expected pathway of care. For example a parent, who is expert in the knowing of his or her child, may pick up early signs of illness which would not be recognised by a stranger or health professional.

Personal

Personal knowledge refers to knowledge of self and what one can or cannot personally do. At a simple level this may relate to the relationships that healthcare professionals develop with patients. As partnership and accountability are more and more evident in the public arena, the paternalistic practices often seen among health professionals in the past are no longer acceptable. This change is one example which may demand that greater attention is paid to personal knowledge in healthcare in the future.

Reference

Downie, R. S. & Calman, K. C. (1987) *Healthy Respect: Ethics in Health Care.* London: Faber and Faber.

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Handout 4.2

Approaches to knowledge development

The natural sciences (positivism)

Aims to test hypothesis

Most scientists use a specific research process to test out hypotheses which they have already generated. This is the way most physiologists, pathologists or biologists work.

Seeks cause-and-effect relations

This school of thought is known as positivism. It tries to establish a cause-and-effect relationship.

Uses measurable concepts

These relationships are sought between two well defined, measurable concepts. The theory generated can be used in many different circumstances.

Based on experimentation and qualitative methods

For such researches, scientists usually:

- use experiments, where the natural environment is manipulated by the researcher
- use quantitative methods.

Naturalism

The interpretative school of thought

Naturalism is sometimes described as the 'interpretative school'.

Things should be studied in their natural state

Naturalism states that the world should be studied in its natural state (as opposed to setting up experiments in which the world is manipulated by the researcher).

Meaning is sought

Naturalism seeks meaning. (Rather than cause-and-effect relationships as in positivism.)

For example, while the positivist view might help to understand how a disease may be combated by a drug, the naturalist approach will provide insight into why some people will or will not comply with taking the drug.

Qualitative methods are used

Naturalist researchers commonly use qualitative methods (such as interviews and observation) in order to collect data.

Critical social theory

Builds on positivist and naturalist knowledge

The last world view, which is gaining interest, is that of critical social theory. Within this framework the vital role of both qualitative and quantitative approaches are acknowledged.

It is context driven, seeking transformation in action.

However, it is argued that the knowledge gained in these ways is 'transformed in practice', according to the specific contextual issues surrounding implementation.

Denies objectivity

Critical social theory rejects the notion of objectivity (highlighted in positivism) on the premise that each one of us will bring some new perspective to the situation under discussion. This should be recognised and built into our understanding of new situations.

Uses action research methodology

Critical social theory is explored through action research, where local solutions are found to local problems. In so doing, all the parties involved learn and move forward.

Handout 4.3

Clinical research designs

Randomised controlled trials

Randomised controlled trials (RCTs) randomly allocate individuals to an active treatment group or to a control group. Randomisation helps to ensure that investigator bias is eliminated. It is for this reason that RCTs are sometimes described as the 'gold standard' of research design.

Any cause-and-effect relationship that is found will be subject to some uncertainty. The larger the number of subjects in the trial, the smaller this uncertainty becomes.

RCTs are commonly used to evaluate the effectiveness of an intervention, eg is a new treatment better than the existing best treatment? However RCTs should only be used where there is a degree of certainty that the two groups under study are comparable, or can be matched in a meaningful way.

They may not be suitable if adverse reactions to a treatment are uncommon, as it would be unrealistic to gather a sufficiently large sample size to gain meaningful results.

Cohort studies

In this approach two groups (or cohorts) of patients are identified, one of which receives the treatment of interest, and one which does not. These two groups are then followed, usually prospectively, and the adverse events that occur in each group are counted.

Cohort studies may be retrospective, but these are not so powerful.

A cohort study may be employed when there is good reason not to undertake an RCT.

Case-control studies

In a case-control study, the investigator gathers 'cases' of patients who have already suffered some adverse event and 'controls' who have not. Both groups are then compared either through direct questioning or through case notes. If those patients who had the adverse outcome were more likely to have undergone the treatment, this would constitute some evidence that the treatment/disease might cause, or precipitate, the adverse outcome.

These studies are particularly useful for rare diseases or events. However, they are not randomised and are retrospective. So they may be liable to bias.

Cross sectional studies

Cross sectional studies are used to establish the accuracy of a diagnostic test. The sample consists of patients who are thought to be harbouring the relevant disorder.

This group of patients will undergo the 'gold standard' test and the new test. The clinician carrying out the new test must be blind to the previous results to eliminate clinical bias. A mathematical formula then allows the comparison of sensitivity and specificity to determine the best diagnostic procedure for a certain disorder.

Qualitative research

Qualitative research is an umbrella term that covers a wide range of specific research designs, all of which study things in natural settings. The method aims to make sense of, or interpret, phenomena in terms of the meanings people bring to them.

The most common qualitative research methods are:

- ethnography
- phenomenology
- grounded theory.

Qualitative approaches are used to:

- generate hypotheses
- identify the range of issues which are of concern to participants
- add validity to previous scientific findings
- ask questions not answerable by quantitative methods.

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Qualitative research as a precursor to quantitative research

Qualitative research is used as a precursor to quantitative research in order to identify the range of issues which may impact on an outcome.

For example, qualitative research may help to identify patient fears of a particular treatment which it would be necessary to account for, should a trial be set up in the future.

Systematic review or meta-analysis

Systematic reviews

It is estimated that up to 1 million RCTs have now been published and the number is ever increasing. Systematic reviews provide a way of consolidating this data.

Each systematic review combines the results of previously published RCTs on a given treatment (or range of treatments) for a given health condition.

When properly carried out, systematic reviews provide the most accurate guide to therapy. However, to be valid, the reviews need to cover as high a proportion as possible of all relevant trials. This can be difficult. For example, Medline may miss about half the published trials.

Systematic reviews generalise the effects of therapy on patients and so may miss specifics, pertinent to individual patients.

Meta-analysis

Meta-analysis involves a statistical analysis of results from combined or integrated clinical trials or studies. Combining studies effectively increases sample size, so reducing any statistical uncertainty about the outcome. Results are presented graphically.

Evidence based practice is not restricted to randomised trials and systematic reviews. It involves tracking down the best available evidence with which to answer the question. Hence when systematic reviews are used, it is critical that note is taken of the inclusion criteria for studies by the authors of the report. In some instances these are rigidly held to the RCT, while other reviewers will use a wider range of study reports.

Handout 5.1

Checklist for appraising a Randomised Controlled Trial

Based on Guyatt, G. H., Sackett, D. L., Cook, D. J. (1993) Users' guide to the medical literature II. How to use an article about therapy or prevention. JAMA **270** 2598–2601 *and* **271** 59–63.

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Is this an RCT that I'm interested in?	☐	☐	☐	☐	☐
Does it address a focused issue in terms of population, intervention and outcomes?					
Was treatment randomly allocated?					
Were all randomised patients accounted for in the results and conclusions?					
(If the answer is no, proceed no further)					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Are the results of the study valid?	☐	☐	☐	☐	☐
Were patients, health workers and study personnel 'blind' to treatment?					
Were the groups similar at the start of the trial?					
Aside from the experimental intervention, were the groups equally treated?					
Reasons:					

What are the results?

Are the results of studies clearly displayed?

What are the overall results of the studies?

How precise are the results?

Summary:

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Handout 5.1 ...*continued*

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Will the results help me in caring for my patients?	☐	☐	☐	☐	☐
Can the results be applied to my patient care?					
Were all the clinically important outcomes considered?					
Are the benefits worth the harms and cost?					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Are the valid results of this randomised trial important?	☐	☐	☐	☐	☐
(Calculations below)					
Reasons:					

CALCULATIONS

	OUTCOME EVENT Yes	No	Total
Control Group	a	b	a + b
Experimental Group	c	d	c + d

Control event rate (CER) = risk of outcome event in control group = $\frac{a}{(a+b)}$

Experimental event rate (EER) = risk of outcome event in experimental group = $\frac{c}{(c+d)}$

Relative risk reduction (RRR) = $\frac{(CER-EER)}{CER}$

Absolute risk reduction (ARR) = $CER-EER$

Numbers needed to treat (NNT) = $\frac{1}{ARR}$

Handout 6.1

Presenting the results of clinical trials

There is a proposal to offer a breast screening programme to women aged 50–64 but there are doubts about the effectiveness.

The following statements about four programmes are derived from four different randomised controlled trials.

On the basis of each statement please indicate (on a scale from 0 to 10) how convinced you are by the evidence presented.

Scale from 0 (not convinced, no support for programme) to 10 (very convinced, support programme).

During a seven year follow up:

- ☐ Programme A reduced the rate of deaths from breast cancer by 34%.
- ☐ Programme B produced an absolute reduction in deaths from breast cancer of 0.06%.
- ☐ Programme C increased the rate of patients surviving breast cancer from 99.82% to 99.88%.
- ☐ Programme D meant that 1,592 women needed to be screened to prevent one death from breast cancer.

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Handout 6.2

Checklist for appraising a Systematic Review or Meta-Analysis Paper

Based on Oxman, A. D., Cook, D. J. & Guyatt, G. H. (1994) Users' guide to the medical literature VI. How to use an overview. JAMA 272 (xvii) 1367–71.

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Is this an overview of trials that I'm interested in?	☐	☐	☐	☐	☐

(If the answer is no proceed no further)

Reasons:

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Are the results of the study valid?	☐	☐	☐	☐	☐

Did the review examine a focused clinical question?

Was the search for relevant studies thorough to ensure that all relevant studies were included?

Were the criteria used to select articles for inclusion appropriate?

Was the methodological quality of studies assessed?

Were the results similar from study to study?

Reasons:

What are the results?

Are the results of studies clearly displayed?

What are the overall results of the studies?

How precise are the results?

Summary:

Handout 6.2 ...*continued*

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Will the results help me in caring for my patients?	☐	☐	☐	☐	☐
Can the results be applied to my patient care?					
Were all the clinically important outcomes considered?					
How precise are the results?					
Reasons:					

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Handout 7.1

Research scenarios

Parents' expectations of doctors scenario

There has been a lot on television and in the newspapers recently about childhood illnesses, particularly about potentially serious ones like meningitis. This has triggered a lot of discussion amongst mothers waiting in the playground to collect their children from school. Mrs Baker told her friends how she had called out the emergency doctor to see three-year-old Lucy at 6 o'clock the previous evening. 'He hardly spent five minutes in the house and just told me to give her Calpol. When she was no better at nine o'clock I took her to the hospital. At least the doctor there examined her properly, shined a light in her eyes and said I wasn't to worry, it wasn't meningitis.'

This scenario accompanies the following article: Kai, J. (1996) What worries parents when their pre-school children are acutely ill, and why: a qualitative study. *BMJ* **313** 983–6.

Harmful effects of smoking scenario

Gareth Evans is 47 and has smoked cigarettes since he first experimented as a schoolboy. He currently rolls and smokes up to 20 cigarettes a day, enjoys smoking and has never tried to cut down or give up. A bout of chronic bronchitis has left him a bit short of breath. At a follow-up visit to the surgery his GP talked about the harmful effects of smoking and that help was available if he wanted to quit. Mr Evans was incensed. 'It's a free country. I can do what I want in my own time. My doctor has no business meddling where it's not wanted.'

This scenario accompanies the following article: Qualitative study of patients' perceptions of doctors' advice to quit smoking: implications for opportunistic health promotion. *BMJ* **316** 1878–81.

Eating in hospital scenario

Rachel Cooper is a six-year-old girl with acute lymphocytic leukaemia. She is half way through her chemotherapy and her consultant is pleased that she is responding well to treatment. He is worried, however, that she seems to be losing a lot of weight. At a team meeting Rachel's nurse commented that Rachel is showing no interest in the food she is given. She comments that, 'more food is returned to the kitchen than is eaten by patients on this ward.'

This scenario accompanies the following article: Holm, L. & Smidt, S. (1997) Uncovering social structures and status differences in health systems. *European Journal of Public Health Medicine* **7** (4) 373–8.

Handout 7.2

Qualitative methods

Grounded theory

In grounded theory, the concepts and theory which emerge from a study are inductively derived from the phenomenon investigated (whereas with deduction, data is gathered to test a predefined theory or hypothesis). Under grounded theory, the starting point is the data – theory is allowed to emerge from that data. An understanding is gained and further investigation is focused onto the relevant issues. Theory is thus 'grounded' in the data, there being no prior hypothesis.

Case study

Case studies involve the detailed investigation of one or more social units (an individual, family or organisation) to explore the key issues involved and the range of variability. They can provide richness and detail but may not be generalisable. Case studies are particularly valuable where broad, complex questions have to be addressed in complex circumstances.

Action research

Action research involves the conscious application of research methods in identifying and addressing a practical problem. A need for change is identified, and cyclical processes are planned, implemented and evaluated in order to meet local need. The people who are actively involved reflect on the process of problem solving to learn from their experience.

Ethnography

Ethnography is the research method which is employed to explore the social and cultural worlds of particular groups. It provides an empirical description of the phenomenon under study within a specific context, helping to throw light on the knowledge, behaviour, beliefs and meanings of that society. In healthcare it may, for example, help to shed light on the way in which different cultures or groups respond to a specific concept such as pain.

Phenomenology

Phenomenological studies strive to understand what is commonly known as 'the lived experience' of a given situation, such as being ill, living with disability or coping with dependence. Thus it seeks to explore the meaning and feelings of participants through the range of approaches to data collection commonly used in qualitative research such as participant observation and unstructured interviews.

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Handout 7.3

Sampling in qualitative research

Sampling

'To select information-rich cases, from which to obtain insight into the issues of importance.'
Scottish Consensus Statement on Qualitative Research in Primary Health Care

Specific criteria
- social
- demographic
- geographic

Theoretical sampling
- list sampling
- snowballing
- multi-purposing
- outcropping
- advertising

1. Theoretical sampling
Theoretical sampling enhances the development of emerging theory by allowing the process to evolve as data is collected. The sample is not pre-determined but allows the research to identify and fill any gaps to develop the analysis.

2. List sampling
Random methods can be applied to select a sample from an existing list although this approach is not commonly applied in qualitative research.

3. Snowballing
The researcher starts with an initial set of contacts who refer on to other potential contacts who in turn refer on, a useful method for studying rare or 'deviant' populations.

4. Multi-purposing
This approach uses existing survey information to reach a group or population of interest.

5. Outcropping
The researcher seeks out specific settings where members of the group of interest meet.

6. Advertising
The sample is obtained from respondents to an advertisement. Because of self-selection there is no control over representativeness or suitability.

Handout 7.4

Qualitative approaches to data collection

1. Non-participant observation
Non-participant observation provides an outsider's view of situations, with data on both behaviour and interactions. It aims to minimise the impact of the research process and is useful to confirm practice in 'real life' and to inform the development of more direct interview questions.

2. Participant observation
In participant observation the researcher gains an inside view of a setting by using relationships with people to explore how the setting is constructed and how it is experienced by the participants. As well as observation of everyday routine events, information can be collected through interviews, informal conversations, surveys and written doucmentation. Acceptance of the researcher into the setting is a prerequisite.

3. In-depth interviews
These range from surveys with fixed lists of questions to unstructured conversations. The term can include any verbal communication between researcher and subject that provides information or further understanding through a two-way discussion.

4. Focus groups
Focus groups are discussions among a purposefully selected group about a specific issue. There is no prior agenda but the group interaction is used to generate data.

5. Contextual data and field notes
Contextual data provides a broader, richer overall picture by giving the context for an individual's or institution's behaviour. Information may be captured in the researcher's contemporaneous field notes or may include written information or special measurements. Field notes refer to any data recorded at the time or immediately after, eg audiotapes which are later transcribed.

6. Critical incident technique
Critical incident technique is used to study memorable events, including rare occurrences that are difficult to observe in practice. The incidents are discussed in detail and their main characteristics mapped out.

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Handout 7.5

Checklist for appraising a Qualitative Paper

Based on, Greenhalgh, T. & Taylor, R. (1997) Papers that go beyond numbers. BMJ ***315*** 740–3.

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Is this an article that I'm interested in?	☐	☐	☐	☐	☐
Does it address a focused issue: statement of aim/research question?					
Is the choice of a qualitative approach appropriate?					
(If the answer is no proceed no further)					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Was the author's position clearly stated?	☐	☐	☐	☐	☐
Did the researcher describe their perspective?					
Did the researcher examine their role, potential biases and influence (reflexivity)?					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Was the sampling strategy clearly described and justified?	☐	☐	☐	☐	☐
Was the method of sampling stated or described?					
Did the investigators sample the most useful individuals and/or settings?					
Were the characteristics of patients defined?					
Reasons:					

Handout 7.5 *...continued*

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Was there an adequate description of the method of data collection given?	☐	☐	☐	☐	☐

Was the method of data collection described?

Was a rationale method given?

How was the data collected? (audiotape/ videotape/fieldnotes)

Were observations taken at different times?

Reasons:

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Were the procedures for data analysis/ interpretation described and justified?	☐	☐	☐	☐	☐

Is there a description of how the themes and concepts were identified?

Was saturation achieved?

Was the analysis performed by more than one investigator?

Were discrepant results taken into account?

Was the data fed back to the participants for comments?

Reasons:

What are the results?

Do the results address the research question?

Are the results likely to be clinically important?

Summary:

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Handout 7.5 *...continued*

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Are the results credible?	☐	☐	☐	☐	☐
Were quotations from the original data presented?					
Is the information available for independent assessment?					
Are the explanations for the results plausible and coherent?					
Have alternative explanations been explored and discounted?					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Will the results help me in caring for my patients?	☐	☐	☐	☐	☐
Can the results be applied to my patient care?					
Were all the clinically important outcomes considered?					
Was the setting in which the study was performed transferable?					
Reasons:					

Handout 8.1

Diagnostic tests

Diagnosis of deep vein thrombosis scenario

David Mitchell is a 48-year-old non-smoker who has just returned from a business trip to Tokyo. He complains to his GP of a swollen and painful right calf. The GP confidently diagnoses a deep vein thrombosis and starts to arrange admission to hospital for anti-coagulation. Mr Mitchell wants to be absolutely sure this is necessary as he has a busy schedule. The GP therefore orders a venogram but at the hospital the radiologist offers ultra-sonography instead. Mr Mitchell is keen to avoid an x-ray but is adamant that he wants certainty in the diagnosis.

Based on Wells, P. S., Hirsh, J. & Anderson, D. R. (1995) Accuracy of clinical assessment of deep vein thrombosis. *Lancet* ***345*** *1326–30.*

Diagnosis of helicobacter pylori infection scenario

Brian Hunter is 48 years old and under threat of losing his job. A lifelong non-smoker, he has recently been getting bouts of upper abdominal pain. These are especially bad after eating Indian food, his favourite. He has recently had to take time off work and knows that he can't afford to take any more. He consults his GP to discuss the alternatives.

Based on Cutler, A. F., Havstad, S. & Ma, C. K. (1995) Accuracy of invasive and non invasive tests to diagnose Helicobacter pylori infection. *Gastroenterology* ***109*** *136–41.*

Diagnosis of acute appendicitis scenario

Stephanie Palmer is 16 years old and in the middle of her GCSEs. Her mother was telephoned from school to collect her early. Stephanie was in tears with lower abdominal pain and had vomited twice. Her mother took her straight to see the GP who told them it might be appendicitis. Stephanie and her mother wanted to know if an operation was really necessary as it would mean missing the rest of her examinations.

Based on Wong, M. L., Casey, S. O., Leonidas, J. C., Elkowitz, S. S. & Becker, J. (1994) Sonographic diagnosis of acute appendicitis in children. *Journal of Pediatric Surgery* ***29x*** *1356–60.*

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Handout 8.2

Assessing the validity of diagnostic test studies

- Has the diagnostic test been compared to a 'gold standard'?
- What was the reference (gold) standard?
- Was the comparison independent and 'blind'?
- Was the diagnostic test validated in subjects with appropriate characteristics?
- Did the test results influence the decision to perform the reference standard?

Handout 8.3

Checklist for appraising a Diagnostic Test Paper

Based on Jaeschke, R., Guyatt, G. H. & Sackett, D. L. (1994) Users' guide to the medical literature III. How to use an article about a diagnostic test. *JAMA* ***271*** *ix* 703–7.

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Is this a diagnostic test I'm interested in? *(If the answer is no proceed no further)*	☐	☐	☐	☐	☐

Reasons:

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Are the results of the study valid?	☐	☐	☐	☐	☐

Has the diagnostic test been compared to a 'gold standard'?

– What is the reference (gold) standard?

– Was the comparison independent and 'blind'?

Was the diagnostic test validated in subjects with appropriate characteristics?

Did the test results influence the decision to perform the reference standard?

Reasons:

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Handout 8.3...*continued*

What are the results? (see Table 1)

Sensitivity	a ÷ (a+c)
Specificity	d ÷ (c+d)
Post predictive value	
Negative predictive value	d ÷ (c+d)
Accuracy	(a+d) ÷ (a+b+c+d)
Likelihood ratio	sensitivity ÷ (1-specificity)

Summary:

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Will the results help me in caring for my patients?	☐	☐	☐	☐	☐
Is the test reproducible, available, affordable in settings appropriate to your patients?					
Does the result alter diagnostic probability sufficiently to lead to changes in patient management?					
Will patients be better off as a result of the test?					

Reasons:

TABLE 1 2 x 2 table for expressing the results for a diagnostic test

	Condition present	Condition absent
Test positive (a+b)	True positives a	False positive b
Test negative (c+d)	False negative c	True negative d

Handout 9.1

Construct a decision tree

- 29-year-old woman, engaged to be married and planning a family, develops occult cervical cancer
- diagnosis confirmed by cone biopsy – moderately differentiated squamous carcinoma, invading 2mm below basement membrane and with lymphatic spread. Primary tumour completely excised with a wide margin of normal tissue around the tumour
- what treatment should she choose?

This scenario is based on Johnson, N., Lilford, R. J., Jones, S. E., McKenzie, L., Billingsley, P. & Songane, F. F. (1992) Using decision analysis to calculate the optimum treatment for microinvasive cervical cancer. *British Journal of Cancer 65* 717–22.

Occult cervical cancer scenario

- Treatment options
  - No further surgery
  - Radical hysterectomy
- Surgical mortality
  - 5 divided by 1000
- Likelihood of disease beyond cone biopsy
  - 2% = 0.02
- Chance of cure by surgery if spread beyond cone
  - 50% = 0.5

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Handout 9.2

Checklist for appraising a Decision Analysis Paper

Based on Richardson, W. S. & Detsky, A.S. (1995) Users' Guides to the Medical Literature. VII. How to use a clinical decision analysis. B. What are the results and will they help me in caring for my patients? *JAMA* ***273xx*** *1610–3.*

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Is this a decision analysis I'm interested in?	☐	☐	☐	☐	☐

(If the answer is no proceed no further)

Reasons:

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Are the results of the study valid?	☐	☐	☐	☐	☐

Are any important clinical strategies or possible outcomes missing from the decision tree?

Are the probabilities for the different options sensible, and based on the best external evidence?

Have the values assigned to outcomes been derived in an appropriate way from credible sources?

Has a sensitivity analysis been carried out to explore the important clinical differences in the probabilities and values?

Reasons:

Handout 9.2...*continued*

What are the results?

Did one course of action lead to a clinically important gain for patients?

Could any uncertainty in the evidence change the result?

Summary:

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Will the results help me in caring for my patients?	☐	☐	☐	☐	☐
Is this decision analysis applicable to my practice?					
Do the probability estimates fit my patients' clinical features?					
Do the utilities reflect how my patients would value the outcomes of the decision?					

Reasons:

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Handout 10.1

Methodologies in economic analysis

Types of economic analysis

- cost minimisation
- cost effectiveness
- cost utility
- cost benefit

Exercise 1 – Cost minimisation

The drug budget for your clinical speciality is overspent. The Head of Pharmacy asks you to review the formulary to see if there are any easy opportunities to reduce spending. You notice that for a certain condition, two similar drugs are being prescribed for patients. The literature suggests that both drugs are equally effective in terms of outcome.

- Drug A costs £10 per day for a 7 day course.
- Drug B costs £15 per day for a 4 day course.
- Your budget for treating this condition is £5,000.

Which drug do you choose?

Cost-minimisation analysis

Assumes that the outcomes or effectiveness of each intervention are equal for a given condition and compares the direct costs attached to each intervention.

Exercise 2 – Cost effectiveness

You have two alternative options for buying fertility treatment

- Option 1 costs £2,500 per try with a 1 in 2 chance of a pregnancy
- Option 2 costs £1,500 per try with a 1 in 4 chance of a pregnancy
- You have a total budget for this of £45,000 and a waiting list of 30 couples

- Which option do you chose?
- How many treatment cycles can you buy?
- How many pregnancies would result from treatment?
- How many couples can you help?

Cost-effectiveness analysis – a definition

Compares costs and outcomes of alternatives within therapeutic categories (but not choices across categories). Outcomes are measured in units, eg lives saved, life years gained, cases identified, pain or symptom-free days, complications avoided. These outcomes are related to the direct costs of the procedure as a ratio, giving cost per unit of effectiveness.

Exercise 3 – Cost utility

You are responsible for commissioning on behalf of your primary care group. Prudent budget management over the past year has resulted in an underspend of £60,000. A number of the group's patients are on waiting lists for elective surgery. Your Board has recommended that the underspend be used to reduce the waiting list, aiming for the maximum health gain for the money. You have information on the costs and the number of Quality Adjusted Life Years for the different procedures.

What do you decide to purchase?

Answer format for cost utility exercise

Item	Number waiting	Cost per item	QUALY per item	Total cost	Total QUALYs	Cost per QUALY
A	20	£500	10			
B	25	£2,000	10			
C	5	£2,500	20			
D	15	£1,500	15			
E	10	£1,000	8			

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Cost-utility analysis – a defintion

Outcome measures combining mortality and morbidity data into a single measure, eg Quality Adjusted Life Year (QUALY). This is a measure of the quantity of life gained by treatment adjusted by increases in the quality of life. It allows comparison of the relative efficiency of healthcare interventions for different conditions.

Some examples of costs per Quality Adjusted Life Year

Treatment	Cost per QUALY (August 1990)
Cholesterol test+diet (age 40–69)	£220
Advice to stop smoking from GP	£270
Antihypertensive treatment to prevent stroke (age 45–64)	£940
Pacemaker implantation	£1,100
Hip replacement	£1,180
Coronary artery bypass graft (left main vessel disease + severe angina)	£2,090
Kidney transplantation	£4,710
Cholesterol test + treatment (age 25–39)	£14,150
Coronary artery bypass graft (one vessel disease + moderate angina)	£18,830

From: Robinson, R. (1993) Cost-utility analysis. *BMJ* **307** 859–62.

Exercise 4 – Cost benefit

- You want to change the way in which you treat stroke patients. Patients are currently admitted under the care of the on-take medical team. Evidence suggests that outcomes are better when care is delivered by an organised stroke unit. You also want to explore the costs and benefits of home-care rehabilitation.
- For the three models of care, list as many costs and benefits as you can think of.

Handout 10.1 ...*continued*

Answer format for cost benefit exercise			
Costs	General Medical Care	Stroke Unit Care	Care at Home
Direct hospital costs			
Indirect hospital costs			
Costs to patient			
Costs to society			
Benefits			
To hospital			
To patient			
To society			

Cost-benefit analysis – a definition

Determines the absolute benefit of a programme and is considered to be the 'gold standard' of economic analysis. All benefits (direct, indirect and intangible) must be valued in the same units as the costs of interventions, usually in monetary terms. Provides information on whether the benefits of interventions outweigh their costs.

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Handout 10.2

Checklist for appraising an Economic Analysis Paper

Based on Drummond, M. F., Richardson, W. S., O'Brien, B. J. & Levine M. (1997) Users' Guides to the Medical Literature. XIII. How to use an article on economic analysis of clinical practice. A. Are the results of the study valid? *JAMA 277 xix 1552–7.*

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Does this study address a clearly defined clinical question about an economically important issue?	☐	☐	☐	☐	☐
(If the answer is no proceed no further)					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Are the results of the study valid?	☐	☐	☐	☐	☐
Is there good evidence cited for the effectiveness of the interventions being compared?					
Was the chosen method of economic analysis appropriate?					
Have all costs and outcomes been identified, properly measured and valued?					
Was a sensitivity analysis performed to test the robustness of the conclusions to uncertainties in the data?					
Reasons:					

Handout 10.2...*continued*

What are the results?

What are the incremental and absolute costs and outcomes of each strategy?

Do costs and outcomes differ between subgroups?

Summary:

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Will the results help me in caring for my patients?	☐	☐	☐	☐	☐

Is this economic analysis applicable to my practice?

Could I expect similar costs in my setting?

Are the treatment benefits worth the harms and the costs?

Reasons:

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Handout 12.1

Checklist for appraising a guideline

Based on Cluzeau, Littlejohns, P., Grimshaw, J. & Feder, G. Appraisal instrument for clinical guidelines. *Version 1, Queen Mary and Westfield College, University of London.*

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Are the reasons for developing guidelines clear?	☐	☐	☐	☐	☐
Are the reasons for developing guidelines clearly stated?					
If so, are these reasonable? (ie large variation in practice, potential for improvement in patient care)					
Are the objectives of the guidelines clearly defined?					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Did the preparation or publication of these guidelines eliminate all potential biases?	☐	☐	☐	☐	☐
Is the agency responsible for the development of these guidelines clearly stated?					
If external funding or support was received, is there any potential bias?					
Was this bias accounted for?					
Reasons:					

Handout 12.1 ...*continued*

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Was the guideline development group comprehensive?	☐	☐	☐	☐	☐

Is there a description of the people involved in the development group?

Did the group contain representatives from all key areas? (ie doctors, nurses, PAMs, pharmacist, health economists, patients, interest groups etc)

Reasons:

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Was all relevant data identified and interpreted adequately?	☐	☐	☐	☐	☐

Is there a description of the sources of data used to select the evidence?

Were the searches for data adequate?

Was the data weighted according to strength of methodology?

Was the weighting appropriate?

Reasons:

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Is the formulation of recommendations adequate?	☐	☐	☐	☐	☐

Is there a description of the methods used to formulate recommendations?

If so, are the methods satisfactory?

Is there an explicit link between the major recommendations and the level of supporting evidence?

Reasons:

Handout 12.1 ...*continued*

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Were the guidelines independently reviewed?	☐	☐	☐	☐	☐
Were the guidelines independently reviewed before publication?					
If so, is information given about methods and how comments were dealt with?					
Were guidelines piloted; if so, how were comments dealt with?					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Has updating of guidelines been addressed?	☐	☐	☐	☐	☐
Is a date given for reviewing and updating?					
Has the body who will be responsible for updating been identified?					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Have individual patient's needs been addressed?	☐	☐	☐	☐	☐
Is there a description of the specific group of patients to which the guidelines are meant to apply?					
Is there a description of the circumstances in which guidelines should not be used?					
Are allowances for patient preferences incorporated into the guidelines?					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Are the recommendations clear?	☐	☐	☐	☐	☐
Are the guidelines clear about the condition to be detected, treated or prevented?					
Are all possible options for management of the condition clearly stated?					
Are recommendations clearly presented?					
Reasons:					

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	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Are likely costs and benefits explored?	☐	☐	☐	☐	☐
Is there an adequate description of the health benefits that are likely to be gained?					
Is there an adequate description of the harms or risks that may occur?					
Is there an estimate of costs for the recommended management?					
Are the recommendations supported if you consider benefit, harm and cost?					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Does the guideline include recommendations for dissemination, implementation and review?	☐	☐	☐	☐	☐
Does the guideline suggest methods for dissemination and implementation?					
Does the guideline suggest clear standards?					
Does the guideline define measurable outcomes that can be monitored?					
Does the guideline identify key elements which need to be considered for local adaptation?					
Reasons:					

Handout 13.1

How are ICPs developed?

- **Identify relevant multi-disciplinary team**
  - and gain their support and involvement. Identify who will act as project manager.
- **Set out expected length of stay**

  Current length of stay needs to be calculated from previous cases.
- **Agree expected clinical goals and outcomes**

  Desired outcomes need to be defined. Care interventions required to achieve these outcomes documented.
- **Each discipline sets out care day-by-day**

  Each discipline should propose its plan of care. These should identify interventions required on a daily basis, based on:
  - current practice
  - national/local guidelines
  - evidence.
- **Collaborative pathway developed**

  Once agreed by the team, each individual plan needs to be combined to produce a collaborative ICP.
- **Build-in patient education**

  Patient education should be built in by defining the needs of patients and identifying appropriate content for teaching.
- **Identify care leader**

  Identify those care leaders who will be responsible for the pathway being followed.

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- **Educate staff and pilot**

  Teaching and support will be needed for the staff. The team needs to be enthusiastic, innovative and receptive to change. Good managerial and clinical support is essential for successful implementation. Any problems that arise should be dealt with as they emerge. Pilot the ICP.

- **Analysis of variance to modify ICP**

  Variance should be analysed. If a recurring variance occurs this may be an indication that the ICP needs to be modified.

The ICP should now be ready for general use, with the support of the project manager.

Handout 13.2

The main advantages of ICPs

Outcomes

Clinical trials have shown that introduction of integrated care pathways:

- reduce LOS
- reduce cost of care
- improve patient satisfaction
- improve quality of care
- identifies research questions.

Other potential benefits that are anecdotal and have not been shown by robust research:

- ensure optimal care and treatment – improved care
- reduce variation in care
- keep patients more informed
- ensure treatment by the right professional at the right time
- provide a clinical audit tool
- strengthen the multi-disciplinary team
- reduce paperwork
- provide an educational tool for new staff/students
- allow prospective planning of required resources.

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Handout 14.1

Checklist for appraising a Quality of Care Paper – Using Audit

Based on Greehalgh, T. Critical appraisal checklist for an article on quality of care. 4th UK Workshop for Teaching Evidence Based Practice .

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Is this an audit I am interested in?	☐	☐	☐	☐	☐
Is the aim of the study clearly stated?					
What is the aim of the study?					
Why was the audit being done?					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
What is current practice?	☐	☐	☐	☐	☐
Was the method of collection of information about current practice adequately described?					
Are all possible options for management of the condition clearly stated?					
Was the method of collection of information about current practice likely to be accurate?					
Reasons:					

Handout 14.1 ...*continued*

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Was development of criteria and standards adequate?	☐	☐	☐	☐	☐

Were the criteria stated?

Was the process of criteria development described?

Was the process of development adequate?

Were the criteria appropriate to the topic?

Were quality standards developed for all criteria?

Reasons:

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
What are the results of the audit?	☐	☐	☐	☐	☐

Are the results adequately described?

What are the results?

Summary:

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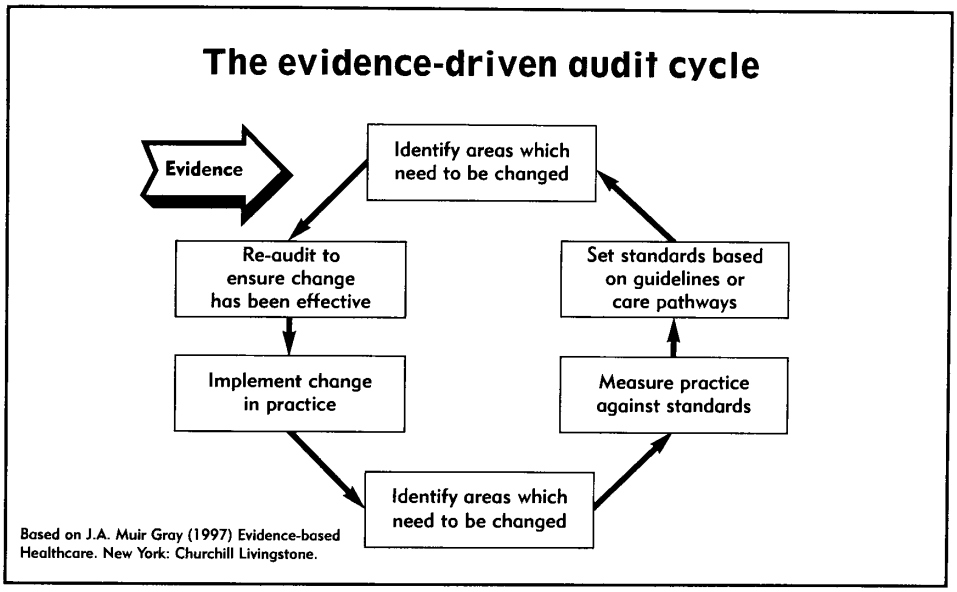
Handout 14.1 ...*continued*

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Was dissemination adequate?	☐	☐	☐	☐	☐
Was the method of dissemination of information about current practice adequately described?					
Was the method of dissemination appropriate?					
Was the dissemination criteria/quality standards adequately described?					
Is the method of feedback of results adequate?					
Was a re-audit carried out after an interval to assess change?					
Reasons:					

	Definitely Yes	Probably Yes	Probably No	Definitely No	No Decision
Will the results help me in caring for my patients?	☐	☐	☐	☐	☐
What are the conclusions of the study?					
Were the conclusions justified by the results?					
Would the conclusions be likely to help my own situation?					
Summary:					

Handout 14.2

Criteria setting



Activity – Criteria setting

Consider the appropriateness of the criteria set out in the audit paper from different user and professional group perspectives (each group to take one role).

- patient interest group
- doctor
- nurse
- audit department staff
- health authority commissioner
- general practitioner

Consider the audit criteria using the following questions:

- are all the criteria appropriate?
- are there any criteria you would OMIT?
- are there any criteria you would ADD?
- how would you go about setting standards?

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Handout 16.1

Project management

The mission

- what is being proposed and why
- why the work is important
- what it is hoped the project will achieve

Action plans

- frame answerable questions by...
- develop search strategy by...
- find and appraise evidence by...
- consider different methods for achieving change, including the means by which achievement can be assessed by...
- develop a strategy for implementation by...
- implementation of evidence into practice by...

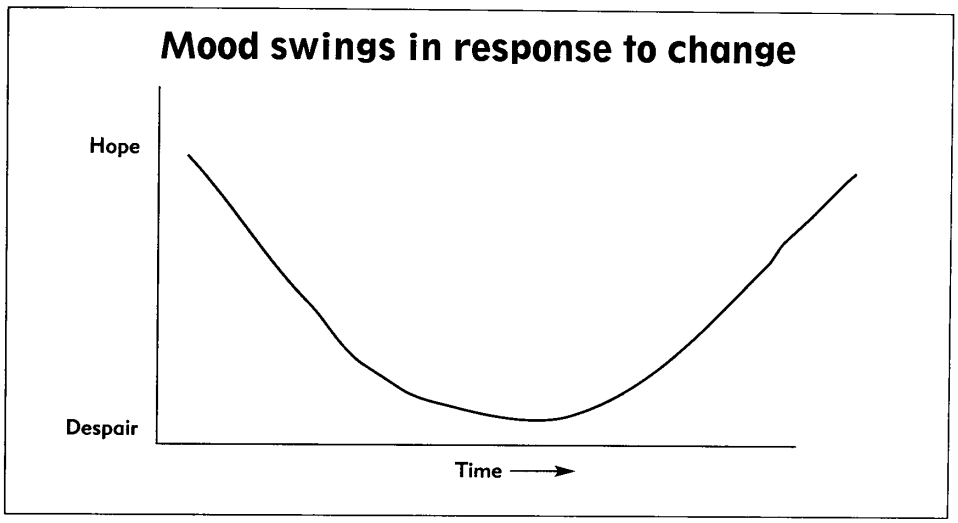
Resource issues

- workforce – who is available to help?
- skills – what is the range of skills needed for both assessing the evidence and introducing change to practice?
- technology – what technology is available to help in accessing data?
- money – are there any positive or negative cost implications related to the proposed change?

Securing support

- who are the stakeholders in this project?
- how will you secure access and support from the stakeholders?
- who may be the main supporters and why?
- who may you have to persuade and how will you do this?
- mood swings in response to change?

Handout 16.1 ...*continued*



Responsibilities of the project leader

- managing the project environment
  - managing human and technical resources
  - delegating responsibility for each specific task
  - minimising opposition
- stating and re-stating the project mission to everyone involved
- maintaining motivation

How should the following issues be handled?

- building relations between team members
- ensuring that individual members take responsibility for allocated tasks with agreed outcomes and deadlines
- ensuring that all team members have a role to play
- building relations with other teams

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Reasons for progress/project meetings

- keep up the momentum of change
- identify any difficulties at an early stage
- allow for rescheduling if necessary
- act as a powerful motivator when different phases are completed
- review planned against actual task achievements
- if targets are not being meet, to explore why this is so eg were original plans too ambitious
- agree what remedial action should be taken if necessary
- revise project plan to the end of the programme
- celebrate achievements to date

Progress meetings can also be used to:

- critically assess the rigour of the evidence
- draw tentative conclusions
- discuss implications for the scope of the project
- decide whether further work is needed.

Handout 17.1

Some comments on change

Of change...

'Predictability... is a thing of the past. Nothing can be taken for granted any more.'
Peters & Waterman, R. H. (1982) *In Search of Excellence*. London: Harper & Row.

Of a potential threat...

'The re-defining of boundaries across and between the professions and between professions and other healthcare workers, combined with more flexible patterns of employment may be interpreted as threatening. They need not be... What must underpin any innovation... is a sound knowledge base, accountable practice and peer review and support.'
Department of Health (1995) *Career Pathways*. London: DoH.

The impact of change

'Violent and accelerating change, now commonplace, will become the grist (corn) of the opportunistic winner's mill. The losers will view such confusion as a 'problem' to be 'dealt' with.'
Peters & Waterman (ibid) (1982)

Of individuals...

'...[they] seek to live in a state of equilibrium.'
Schein, E. (1969) The mechanism of change. In: W. G. Bennis (Ed) *Planning Change*. New York: Holt, Reinhart & Winston.

Equilibrium in organisations...

'...work as a result of a dynamic balance of forces working in opposite directions with equal pull.'
Lewin (1951) Group Decisions and Social Change. In: Swanson *et al.* (Eds) *Readings in Social Psychology* (2nd Ed) pp459–473. New York: Holt, Reinhart & Winston.

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Handout 17.2

Force field analysis

'A technique for seeking consensus about the critical factors related to a specific issue.'

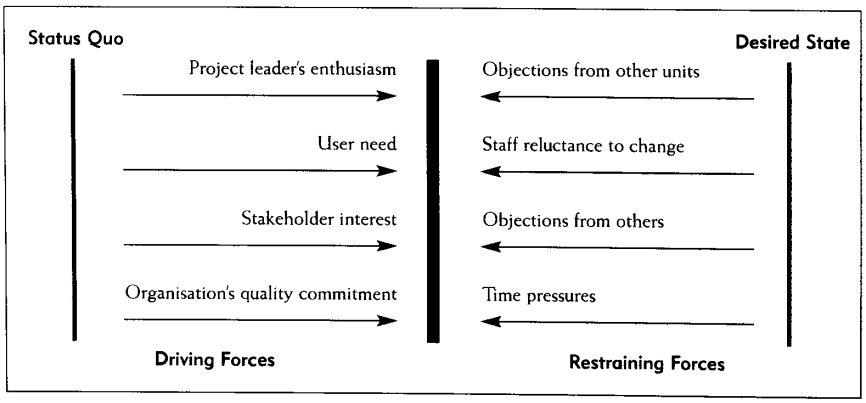
Step 1
Driving and restraining forces – examples

- management support
- resources
- organisational support
- organisational culture
- interprofessional relations
- purchaser support
- user expectations
- organisational, professional and government agendas
- pressure of time

Step 2
Divide your list up into major categories which may be helpful in your analysis

- personal factors
- team factors
- organisational factors

Step 3 Draw the force field chart



Step 4
Review the chart

In the final stage, each side of the chart is reviewed in turn, asking the questions:

Driving forces

- which forces can be strengthened?
- how can this be done?

Restraining forces

- which forces can we do nothing about? Ignore these factors
- which forces can we do something to undermine or weaken?
- how can this be done?

It is worth noting that it is better to reduce restraining forces than to try to strengthen driving forces – it is the restrictions that can stop changes happening.

Methods of getting people on board

Rational-empirical

The rational-empirical view of change is based on the premise that all action can be guided by reason. Thus, if there is a research base for a particular practice, then it will be used because that is the logical thing to do. In this case power comes from possessing knowledge.

Power-coercive

In the power-coercive model, power is vested in status and control. Essentially there is an assumption that people with less power will comply with the will of those with greater power.

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Normative re-educative

The normative re-educative model contrasts these two 'top down' views and is probably the one which would be most attractive to healthcare professionals. Essentially it works on the premise of local involvement, shared exploration of need and involvement in decision-making, which is reflected in the move to patient-centred care and partnerships in decision-making.

Choosing between the approaches

It has to be said that no one approach works all of the time – even if one feels ideologically right for you. If one approach always worked, there would not be a smoker left in the world and everyone would clean their teeth after meals. But human nature is just not like that. Hence in reality, and with a full awareness that these things take time and energy, systematic plans are needed to minimise resistance and maximise strengths.

Cascading Evidence
into Practice

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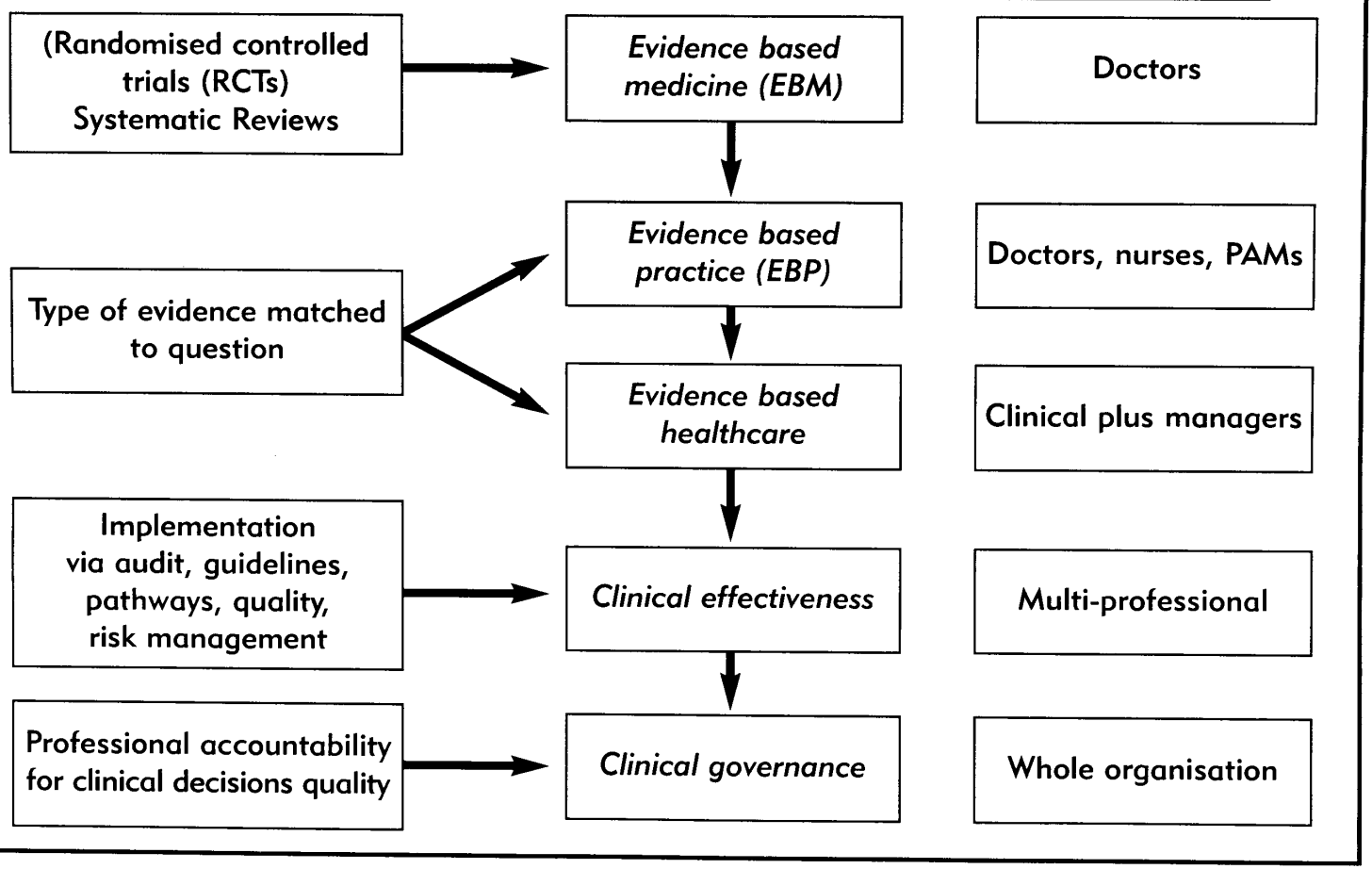
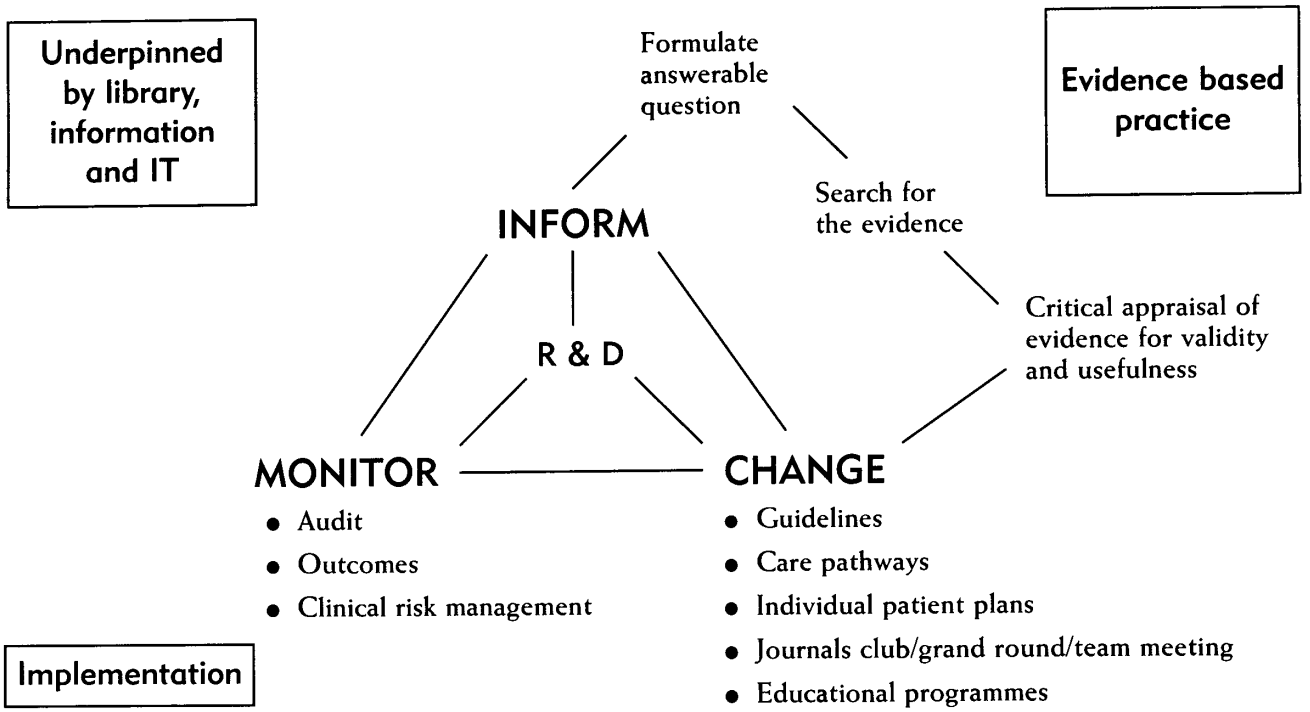
Slide 1.1

Terminology



Slide 1.2

Clinical Effectiveness

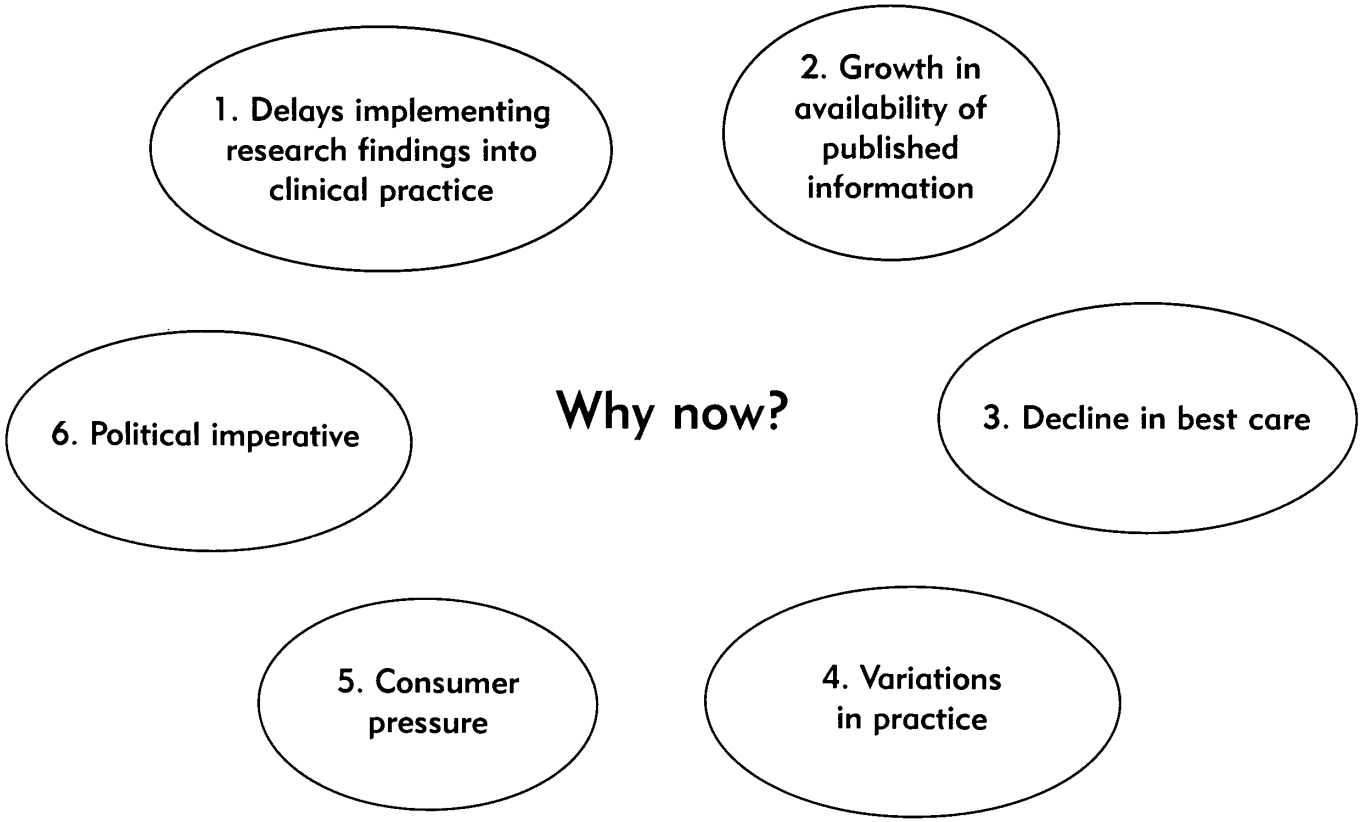


- Audit
- Outcomes
- Clinical risk management

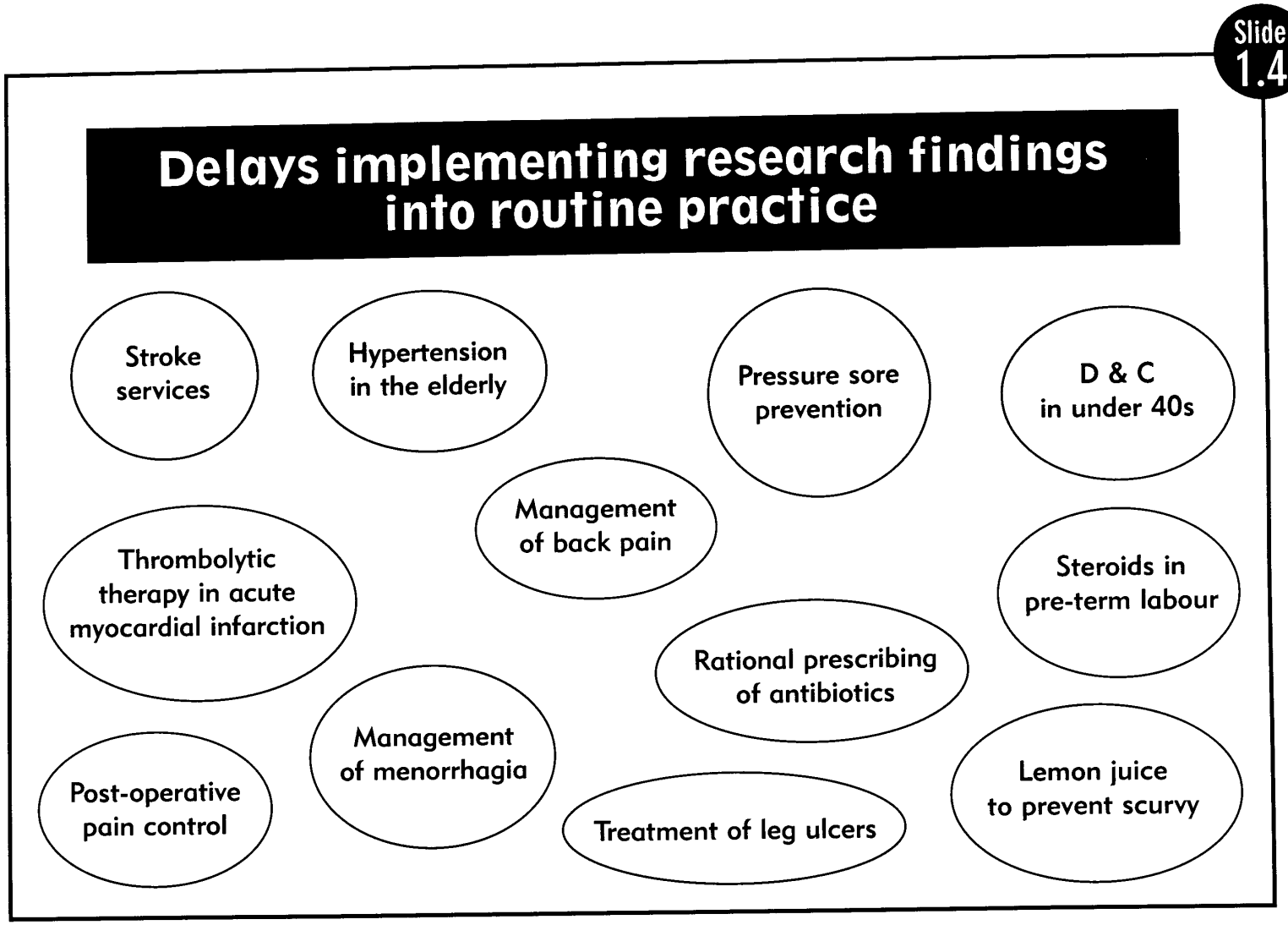
- Guidelines
- Care pathways
- Individual patient plans
- Journals club/grand round/team meeting
- Educational programmes

Slide 1.3

Factors Contributing to the Promotion of Evidence Based Practice



Slide 1.4



Slide 1.5

Time spent reading clinical material
(on average per week)

● Medical students	60–120 minutes
● House officers	0–20 (up to 75%=none)
● SHOs	10–30 (up to 15%=none)
● Registrars	10–90 (up to 40%=none)
● Senior Registrars	10–45 (up to 15%=none)
● Consultants	
post 1975	15–60 (up to 30%=none)
pre 1975	10–45 (up to 40%=none)

From: Sackett, D., Richardson, W. S., Rosenberg, W. & Haynes, R. B. (1997) *Evidence Based Medicine – how to practice and teach EBM*. New York: Churchill Livingstone.

Slide 1.6

Clinical Governance

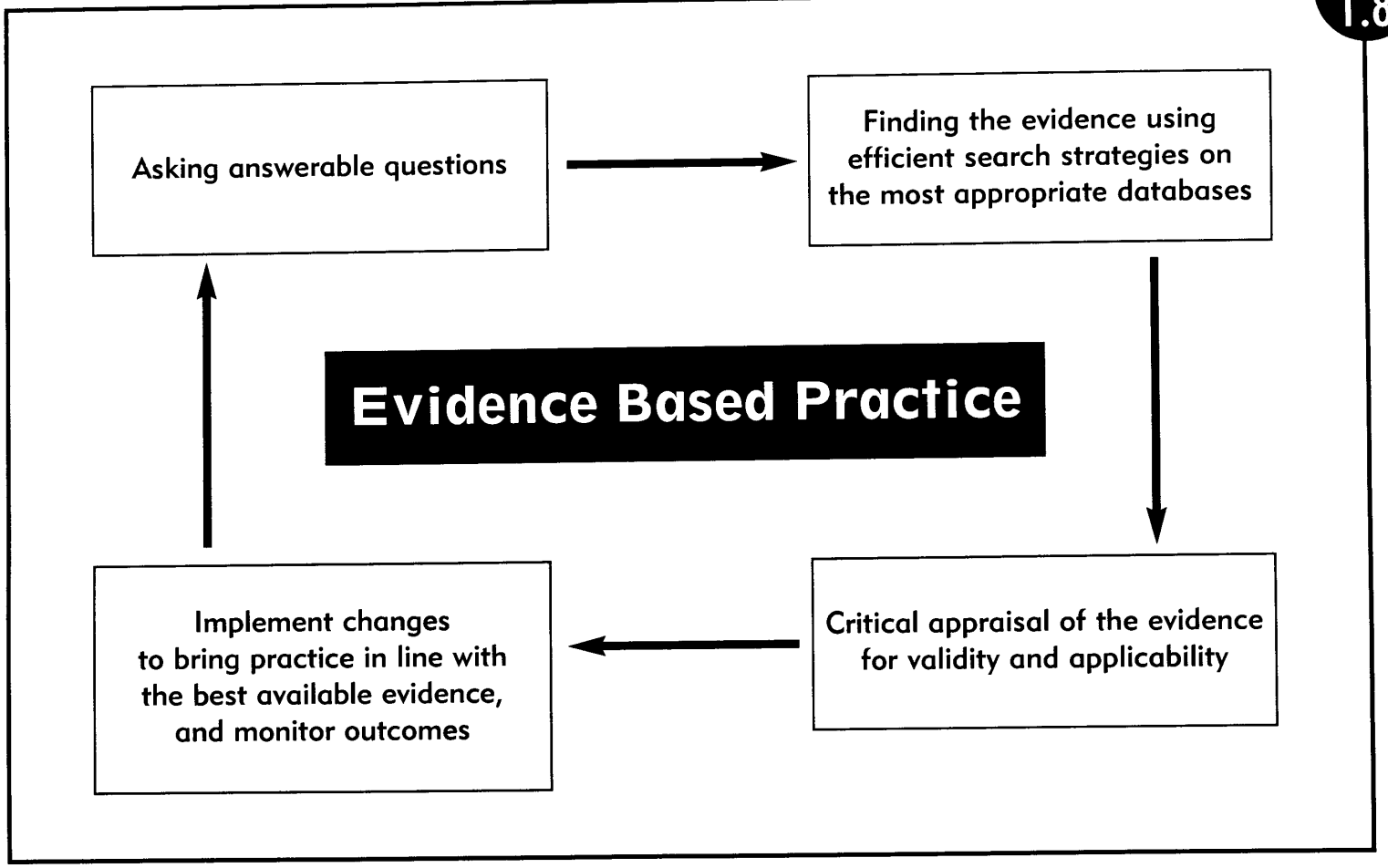
'Action to ensure that risks are avoided, adverse events are rapidly detected, openly investigated and lessons learned, good practice is widely disseminated and systems are in place to ensure continuous improvements in clinical care.'

From: *The New NHS Modern Dependable* (1997)

Main components of clinical governance

- Outlines clear lines of responsibility and accountability for the overall quality of care
- A comprehensive programme of quality improvement activities
- Clear policies aimed at managing risks
- Procedures for all professional groups to identify and remedy poor performance

Slide 1.8

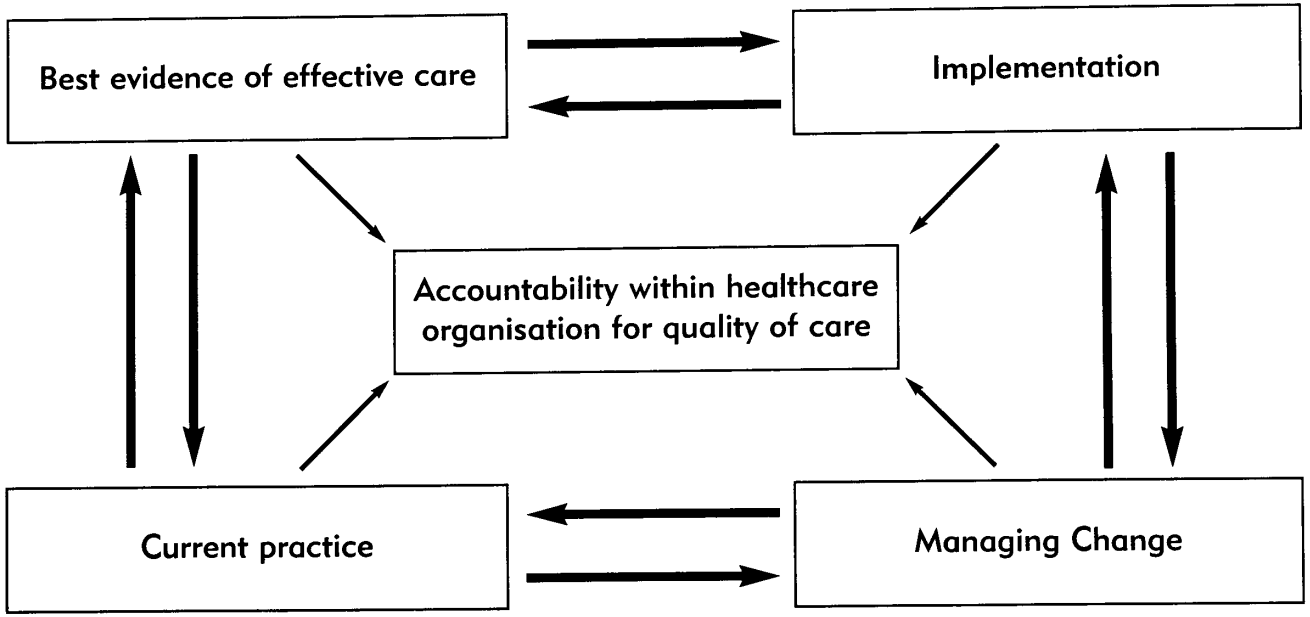


Slide 1.9

Ensuring good practice in line with the best available evidence

Slide 1.10

Towards Clinical Governance



Slide 2.1

Asking Answerable Questions – PICO

Component	*Key step*	*Example*
Patient Problem population	How would I succinctly describe a group of similar patients?	In children under 12 years with condition X...
Intervention (test, treatment, process of care)	What is the main action I am considering?	...would adding drug Y to their current therapy...
Comparison or alternative	What is/are the other option(s)?	...compared to increasing the dose of their current therapy...
Outcome	What do I/ the patients want or not want to happen?	..lead to increased symptom control with no increase in side effects?

From: Sackett D. L. *et al.* (1997) *Evidence Based Medicine – how to practice & teach EBM*. New York: Churchill Livingstone.

Slide 3.1

General sources of evidence	What we need to filter out
• published information	• letters
• personal experience	• editorials
• unpublished information	• case studies
• ongoing research	• chatty articles
• 'grey' literature	• opinions
• colleagues' advice	• non-research based articles
• email discussion lists	• news columns

Slide 3.2

A Medline filter to find RCTs

1 controlled clinical trials/

2 randomized controlled trials/

3 experimental research design/

4 multicenter studies/

5 single-blind method/

6 randomized controlled trial.pt.

7 clinical trial.pt.

8 ((single or double or treble or triple) adj5 (mask$ or blind$)).tw.

9 placebos/or placebo$.tw.

10 or/1–9

Slide 3.3

A Medline filter to find systematic reviews

1 review, academic.pt.

2 meta-analysis.pt.

3 (systematic$ adj5 review$).tw.

4 (systematic$ adj5 overview$).tw.

5 meta-analysis/

6 meta-analysis.tw.

7 or/1–6

Slide 3.4

Join with the filter:

1 controlled clinical trials/

2 randomized controlled trials/

3 exp research design/

4 multicenter studies/

5 single-blind method/

6 randomized controlled trial.pt.

7 clinical trial.pt.

8 ((single or double or treble or triple) adj5 (mask$ or blind$)).tw.

9 placebos/or placebo$.tw.

10 or/1–9

11 smoking/

12 smoking cessation/

13 nicotine/

14 (nicotine adj replacement).tw.

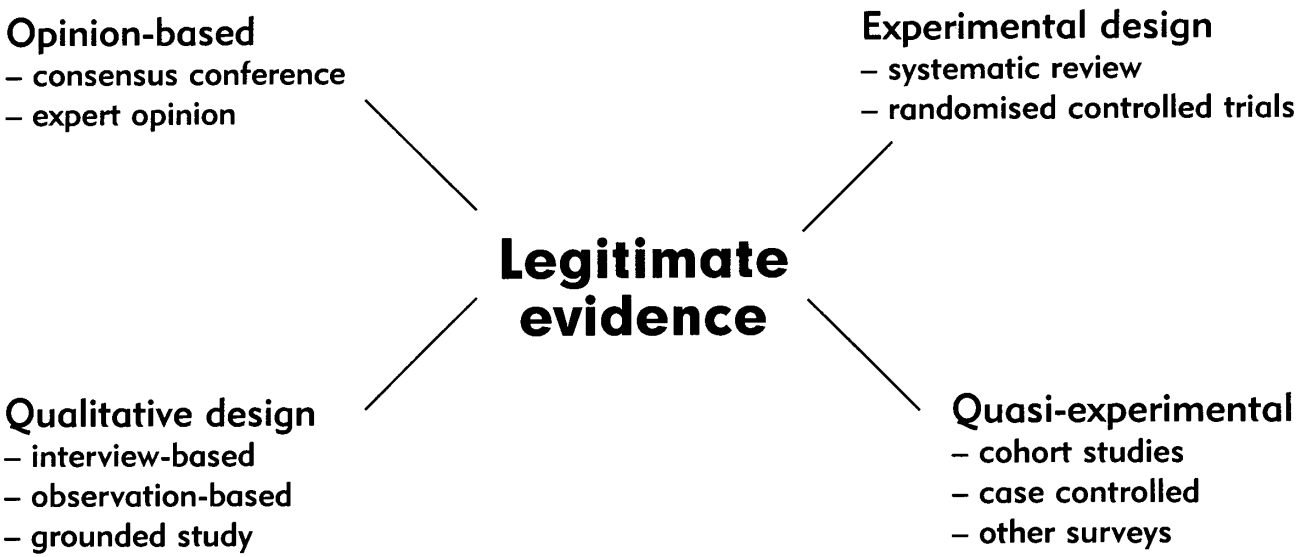
15 patches.tw.

16 15 and (14 or 13 or 12 or 11)

17 10 and 16

Slide 4.1

Spectrum of evidence



Slide 4.2

Clinical Research Designs

- qualitative research
- case-control studies
- cross sectional studies
- systematic review or meta-analysis
- cohort studies
- randomised controlled trials

Slide 4.3

What type of study is most appropriate to answer the following questions?

- Why do patients call their GP out of hours?
- Does paternal exposure to ionising radiation before conception cause childhood leukaemia?
- What is the most sensitive and specific method of screening for genital chlamydial infection in women attending in general practice?
- Does laproscoic cholecystctomy cause less morbidity and a swifter return to work than small incision cholecystectomy?
- For a given patient with asthma, does beclomethasone give better symptomatic control than fluticasone?
- How does smoking cessation affect the risk of stroke in middle aged men?

Randomised Controlled Trials

'An RCT is the best way of evaluating the effectiveness of an intervention, but before an RCT can be conducted there must be equipoise – that is, genuine doubt about whether one course of action is better than another'

Muir Gray (1977) *Evidence based healthcare*. New York: Churchill Livingstone

Slide 5.2

Observation is susceptible to bias

Treatment A is found to work better than treatment B

- Treatment A might have been given to healthier patients ⇒ **Selection bias**
- Treatment A might be a new drug, thought to be better ⇒ **Measurement bias**
- Treatment A might taste better, increasing compliance ⇒ **Confounding bias**

Slide 5.3

Steps of a randomised controlled trial

1 Defining the hypothesis

2 Selection

3 Informed consent

4 Entry

5 Random allocation

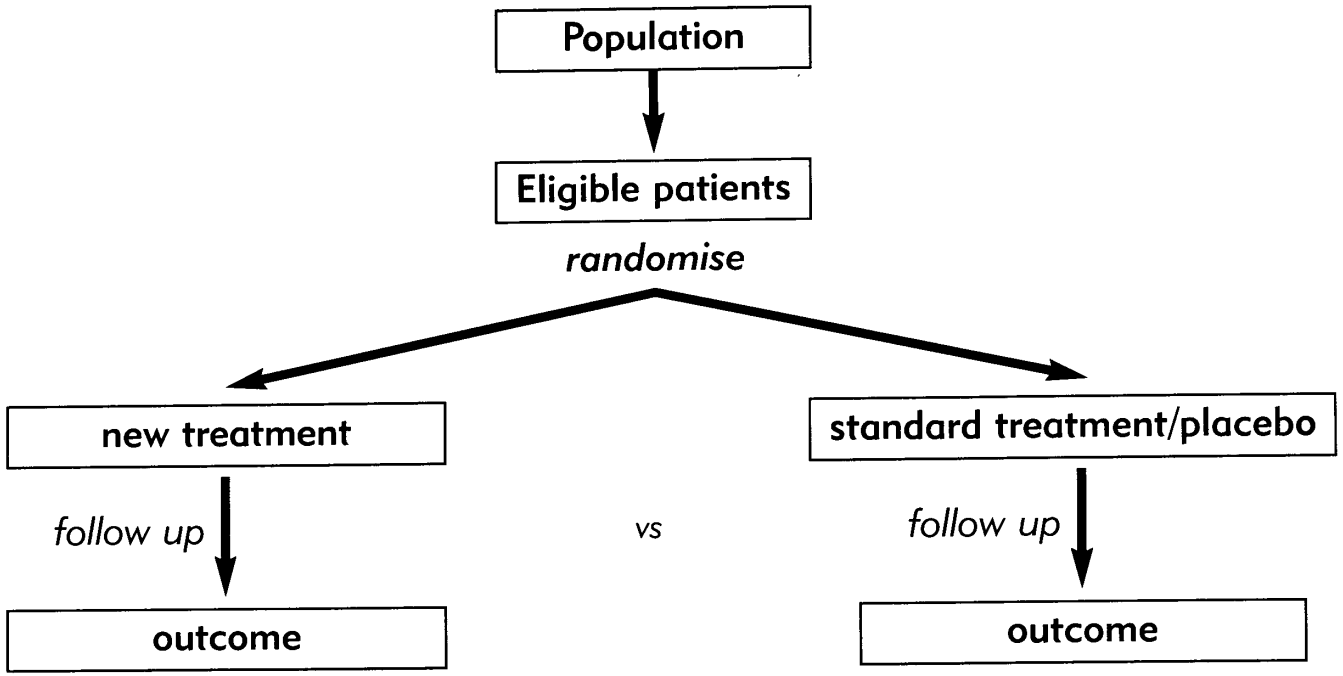
6 Treatment

7 Comparison of outcomes

– Analysis based on intention to treat

Slide 5.4

Randomisation helps eliminate bias



Slide 5.5

Questions to ask of an RCT

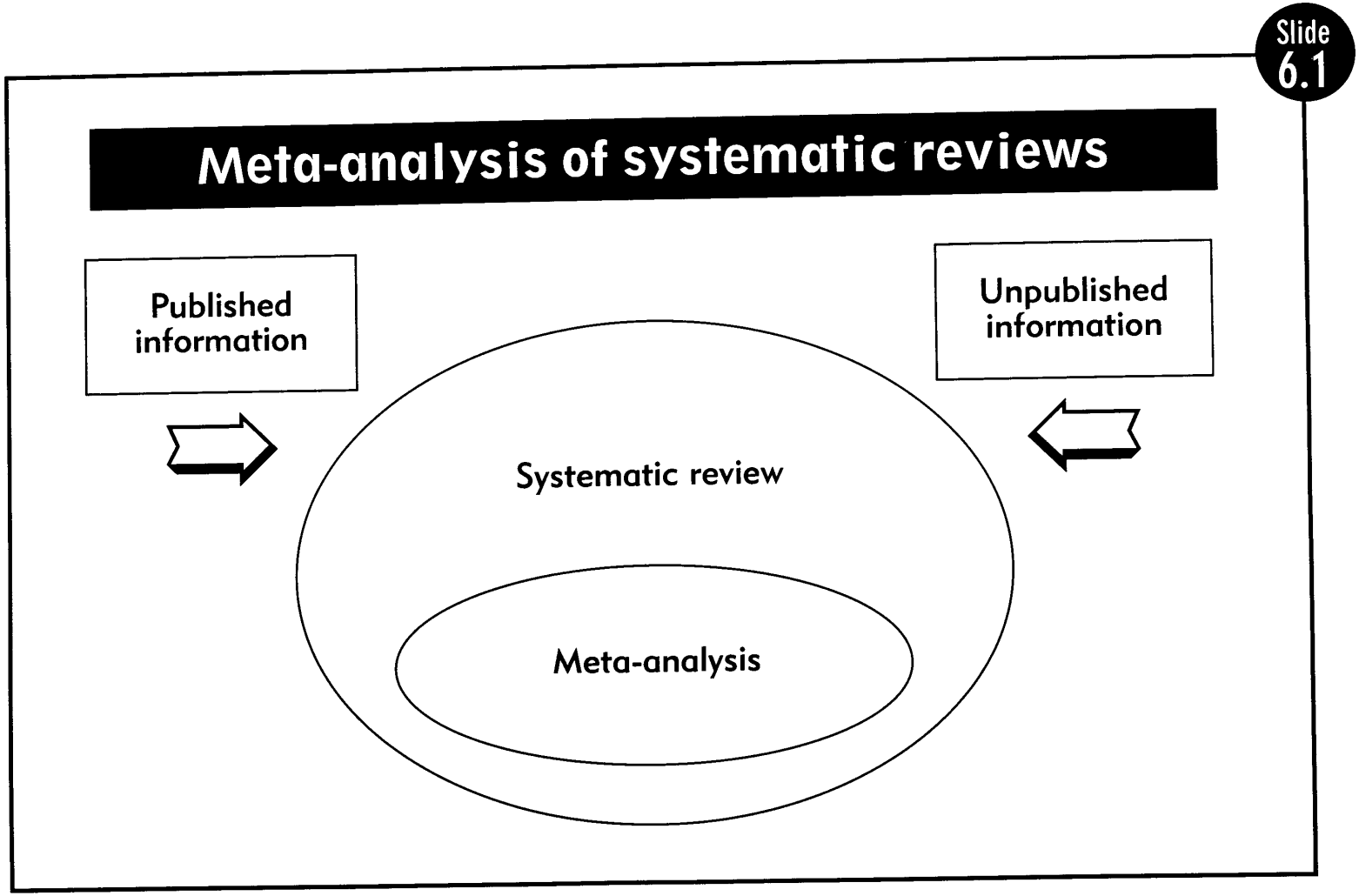
When considering statistical analysis of an RCT, there are three basic concepts which participants need to understand about the results:

1 Are the results owing to chance?

2 How precise are they?

3 Are they statistically significant?

Slide 6.1



Meta-analysis in systematic reviews

- the statistical analysis which combines or integrates the results of several independent clinical trials or studies examining the same question
- strict protocols to define methods
- dependent on identifying all possible studies for inclusion, whether published or not
- increases statistical power by increasing sample sizes
- resolves controversy when studies disagree
- answers new questions not previously posed in individual studies
- improves estimates of the size of effect
- results presented graphically

Slide 6.3

A 'Blobbogram' or Forest plot

Slide 6.4

Odds – definition

'The number of patients who fulfil the criteria for a given endpoint divided by the number of patients who do not.'

Odds ratio – definition

'Odds ratio compares the odds of a dichotomous outcome in two different groups.'

Egger, M., Davey Smith, G. & Phillips, A. N. (1997) *British Medical Journal* **315** 1533–7.

Slide 7.1

Qualitive research: a definition

'The goal of qualitative research is the development of concepts which help us to understand social phenomena in natural (rather than experimental) settings, giving due emphasis to the meanings, experiences, and views of all participants.'

Mays, N. & Pope C. (Eds) (1996) *Qualitative Research in Health Care*. London: British Medical Journal Publishing Group

Slide 7.2

Why do qualitative research?

Purpose

Understanding processes through which behaviours, systems or relationships are changed or sustained.

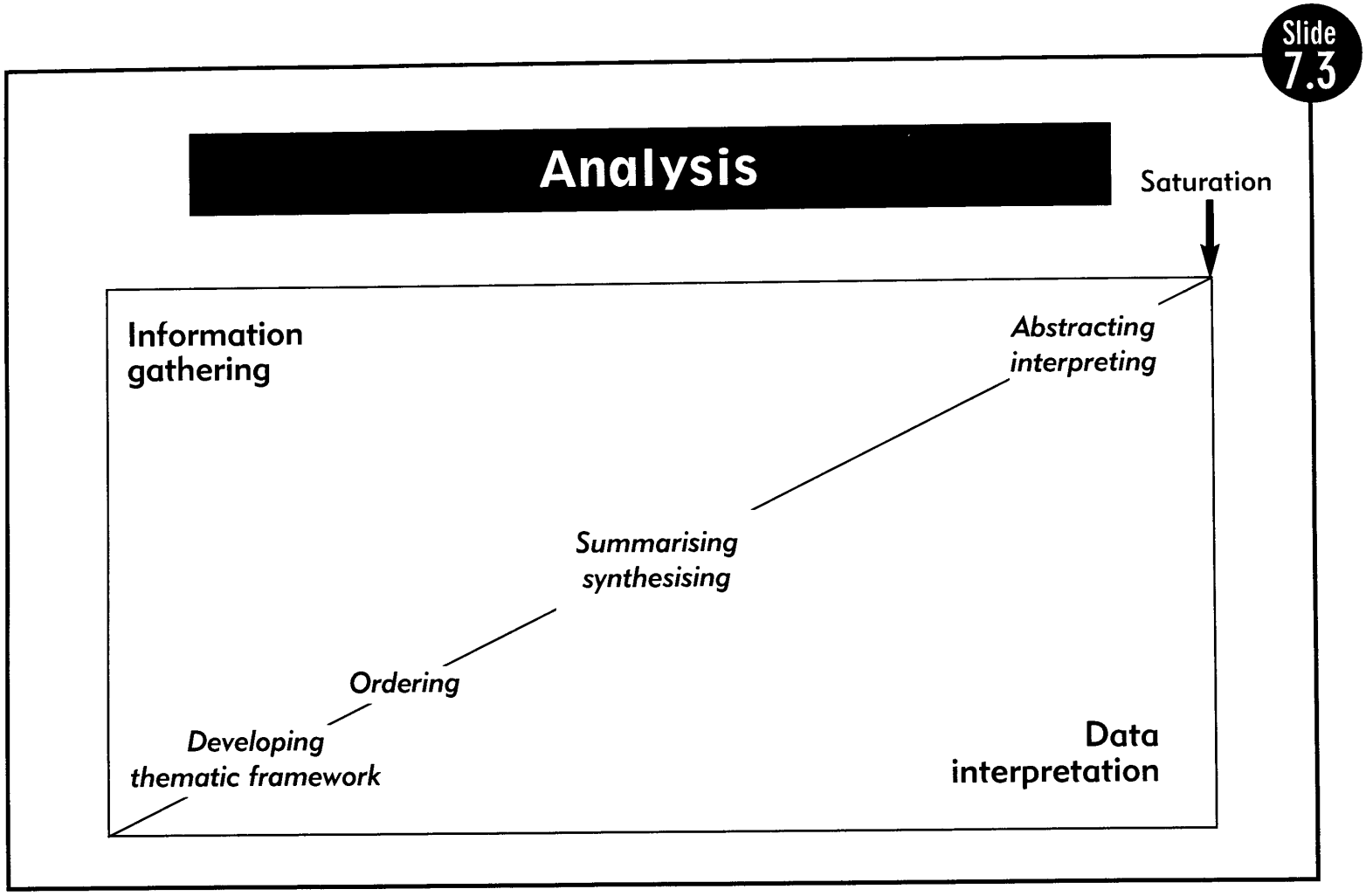
Context

Studying and interpreting people's behaviours, opinions and interactions in their normal context bridges the gap between what people say they do and what they actually do in practice.

Meaning

People's interpretation of events, experiences and relationships change with context – qualitative research allows meanings to be placed in context.

Slide 7.3



The overstated dichotomy between quantitative and qualitative methods

From: Mays, N. & Pope, C. (1996) *Qualitative research in health care*. BMJ Publishing Group.

	Qualitative	Quantitative
Social theory	Action	Structure
Methods	Observation/Interview	Experiment/Survey
Question	What is X?	How many Xs?
Reasoning	Inductive	Deductive
Sampling	Theoretical	Statistical
Strength	Validity	Reliability

Slide 7.5

Qualitative methods – their role

'Randomised controlled trials may constitute the ideal of experimental design, but they alone cannot prove that the right intervention has been provided to the right patient at the right time and place. ...Issues that are complex, multidimensional, and grounded in individual experience lend themselves to study by descriptive and qualitative methods.'

Greenhalgh, T. (1996) *Is my practice evidence-based?* British Medical Journal **313** 957–8.

Assessing the usefulness of diagnostic tests

	Condition present	Condition absent	Total
Test positive	True positive	False positive	All test positives
Test negative	False negative	True negative	All test negatives
Total	All condition positives	All condition negatives	Total population

Slide 8.2

Assessing the usefulness of diagnostic tests

	Condition present	Condition absent	Total
Test positive	a	b	a+b
Test negative	c	d	c+d
Total	a+c	b+d	a+b+c+d

Slide 8.3

Taking a test that is 80% sensitive and 70 % specific

Prevalence of condition	Positive Predictive Value of test
50%	73%
10%	23%
1%	3%

Slide 8.4

Likelihood ratio

...is the likelihood of
that test result in people with the disease
compared with
that test result in people without the disease.

likelihood ratio (positive test result)
= sensitivity/1-specificity
= true positive/false positive

Balance between sensitivity and specificity

SpPin

a highly **S**pecific test with a **P**ositive result
rules **IN** the diagnosis

SnNout

a highly **S**ensitive test with a **N**egative result
rules **OUT** the diagnosis

Slide 8.6

Assessing the applicability of diagnostic tests

- Is the test reproducible, available and affordable in settings appropriate to your patients?
- Does the test result alter diagnostic probability sufficiently to lead to changes in patient management?
- Will patients be better off as a result of the test?

Slide 9.1

Decision analysis – definition

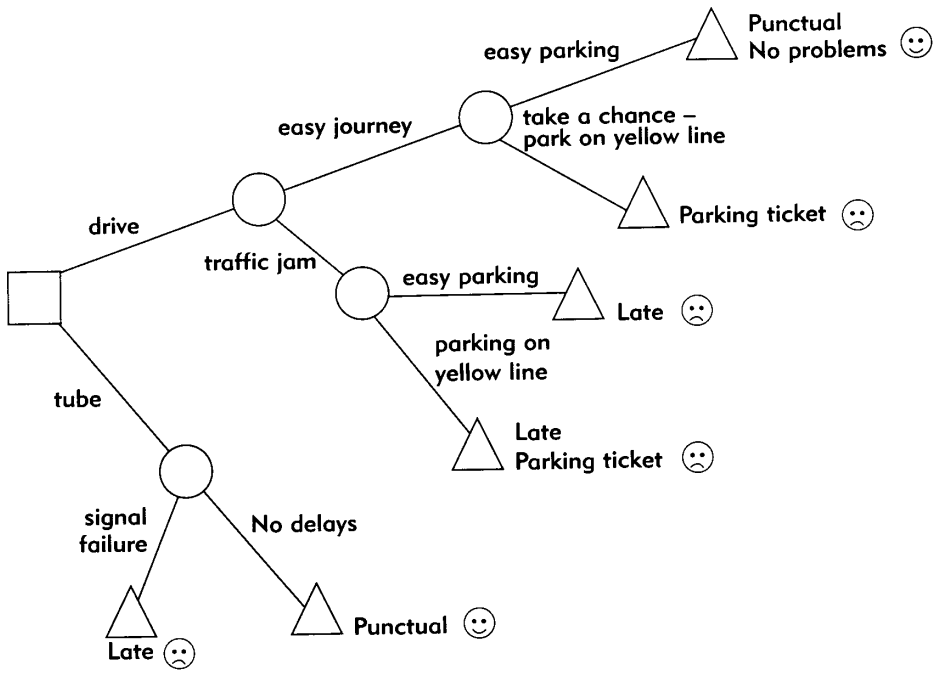
'Decision analysis is a method for breaking complex problems down into manageable component parts, analysing these parts in detail, and then combining them in a logical way to indicate the best course of action.'

Lilford, R. J. (1992) *BMJ* **304** 1099–1103.

Slide 9.2

How will I get there?

An example of a decision tree of how to get to a venue



What can decision analysis be used for?

- patient management: diagnosis, treatment, prognosis
- policy making
- prioritising topics for research
- systematic reviews
- guideline development
- diagnostic strategies
- teaching

Slide 9.4

Decision analysis – a useful tool

- bridges gap between pure critical appraisal and the complexity of real life medicine
- essential components include:
  - consideration of all options
  - identification of all possible outcomes
  - application of values to outcomes, including patients' values
  - flexibility in applying evidence with room for clinical judgement

Slide 9.5

Deciding on a treatment

- You wish to explain the implications of two alternative treatment options, namely surgery or chemotherapy, to a 45-year-old man with cancer.
- If the choice is surgery, he has a 2% chance of dying as a result of the operation, a 50% chance of being cured with a life expectancy of 15 years and a 48% chance of not being cured with a life expectancy of 1 year.
- If the choice is for chemotherapy there is a 5% chance of death, a 65% chance of cure with a life expectancy of 15 years and a 30% chance that the progression of the cancer will be slowed but not cured with a life expectancy of 2 years.
- To assist in making a decision construct a decision tree to calculate the expected value of each option in terms of life expectancy.

Slide 9.6

Adding value to the decision tree

- To allow for trade-off between different outcome
- Examples include:
  - multiple gamble techniques
  - rating scale measurements
  - *Sackett thermometer*
  - standardised surveys
    - *Euroqol*
    - *SF36*
    - *Nottingham Health Profile.*

Adding value to the decision tree

- Use a thermometer as an example to rate the desirability of the following outcomes

  Between 0 (least desirable)

  and 100 (most desirable)

- Outcomes include:
  - fertile life
  - life but infertile after surgery
  - immediate surgical death
  - cancer death after surgery and infertility
  - cancer death after period of fertility.

Slide 9.8

Decision analysis conclusions

- framework: aid in analysis of complex problems
- consider *all options* and *all possible outcomes*
- apply *values* to outcomes
- *explicit* application of best available evidence
- *bridges gap* between purely critical appraisal and realities of day-to-day practice

Slide 10.1

What is economic analysis?

- A technique to assist decision-making when choices have to be made between several courses of action
- Economic analyses help define choices in resource allocation

Slide 10.2

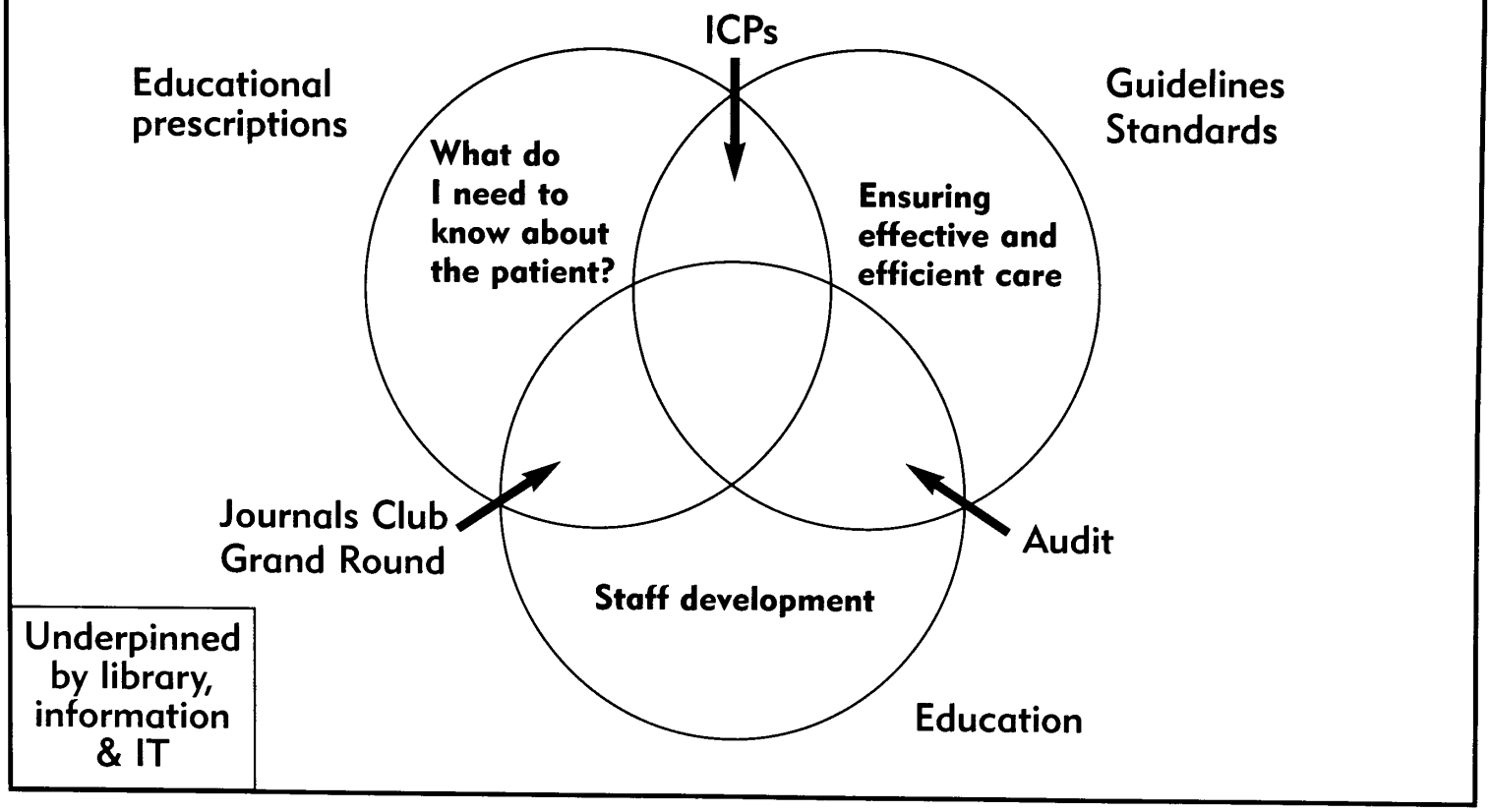
Opportunity cost

'Given that resources are scarce, if we decide to use them in one particular way there is an opportunity forgone to obtain the benefits of using these resources in some other way.'

Gavin Mooney (1992) *Economics, Medicine and Healthcare (2nd edition)*. Hemel Hempstead: Harvester Wheatsheaf.

Slide 11.1

Effective clinical care



Slide 11.2

Summary for local implementation

- **disseminate** to all relevant people
- **adapt** to meet local needs/skills mix
- **adopt** ways of thinking about care
- **implement** new practice
- **monitor** process of care
- **evaluate** outcomes

– The evolution of clinical audit: *NHS Executive booklet*.

Slide 12.1

Guidelines are...

'systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.'

Field, M. J. & Lohr, K. N. Guidelines for clinical practice. From *Development to Use*. National Academy.

Slide 12.2

The aims of clinical guidelines

- To improve patient care by:
  - making evidence based standards accessible to clinicians
  - helping clinical decision-making to be more objective
  - educating patients and professionals abut current best practice
  - taking into consideration patient preferences
- To improve cost-effectiveness of health management
- To provide a benchmark for disease management

Slide 12.3

Guidelines are more likely to be effective if they ...

- **take into account local circumstances**
  - adapt guidelines to meet local needs and skills mix
  - need involvement of locally respected clinician and end users
- **are disseminated by an active educational intervention**, including seminars, educational outreach visits and use of opinion leader
- **are implemented by patient-specific reminders relating directly to professional activity**
  - operate directly upon the consultation
  - offer patient-mediated interventions

Grimshaw, J. & Russell, I. (1993) Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet* **342** 1317–22.

Slide 13.1

Integrated care pathways

Integrated care pathway – a definition

'Defines the optimal sequence and timing of interventions by physicians, nurses and other staff, for a particular diagnosis or procedure.'

Integrated care pathways are also known as...

- care protocols
- critical pathways
- anticipated recovery pathways
- collaborative care plans
- care maps
- multi-disciplinary action plans
- collaborative care tracks

Slide 13.2

What an ICP does

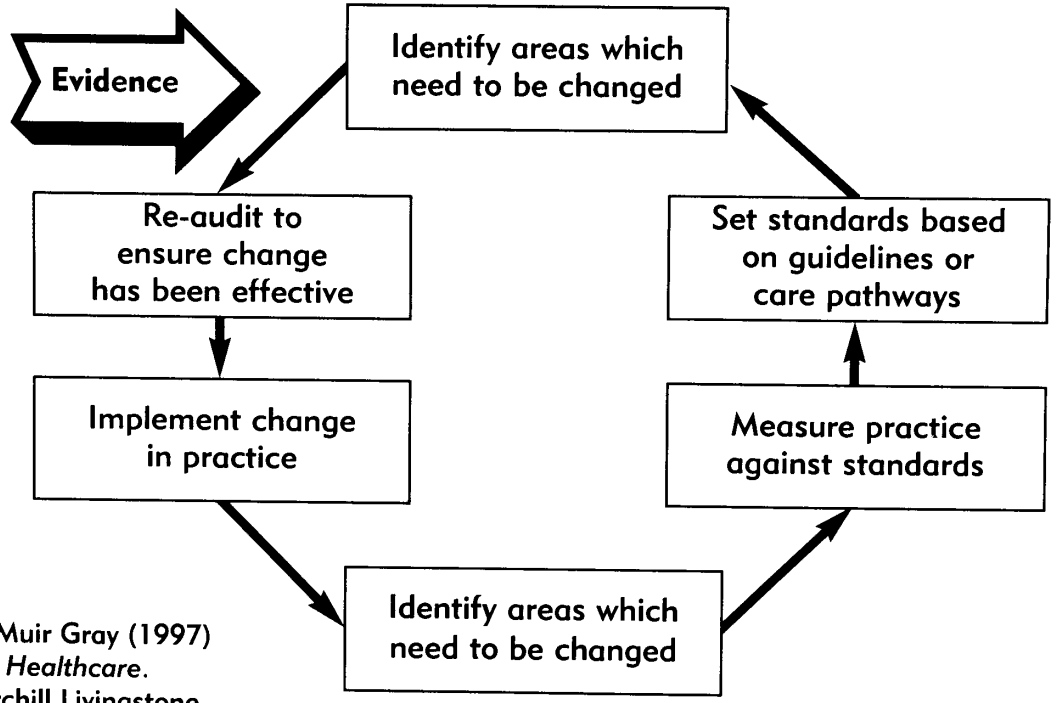
- automatically becomes part of care
- divides care into time intervals during which specific tasks are indicated to achieve goals/outcomes
- outlines care for the whole multi-disciplinary team
- encourages discharge planning
- allows for variation
- includes patient protocols
- eesearch protocols can be included

Slide 13.3

Prerequisites for an ICP

1. **Evidence-based**
   ICPs should be based on evidence (where available), current practice and patient needs.
2. **Collaborative**
   The successful development and implementation of an ICP requires collaboration and agreement of the multi-disciplinary team. This will lead to clarification of roles and a better understanding of each other's professional responsibilities.
3. **Documentation for variance, used as an audit tool**
   Space must be available to document variance. This can be used as an audit tool. ICPs should be regularly audited and pathways altered if there is a frequently occurring variance.
4. **Discharge planning included**
   Steps for discharge planning should be included along the path to prevent administrative delays on discharging patients.

The evidence-driven audit cycle



Based on J. A. Muir Gray (1997)
Evidence-based Healthcare.
New York: Churchill Livingstone.

Slide 14.2

Audit and research – the difference

Research – What is the right thing to do?

Research asks 'What is the right thing to do?' –
a question about practice.
It defines a hypothesis.

Audit – Am I doing the right thing?

Audit asks 'Am I doing the right thing?'
It looks at practice as it stands.

Slide 15.1

Definition of an outcome

'Attributable effect of intervention or its lack on a previous health state'

Based on the work of Dr Azim Lakhani at the Central Health Outcomes Unit, Department of Health.

Slide 15.2

Why use outcome indicators?

- Quality monitoring
- They allow us to objectively decide upon best clinical care
- Achieving cost effectiveness
- Outcomes measures are important in deciding upon cost effectiveness and cost benefit
- Maximising health gain for available resources
- They allow us to move away from cost minimisation which bears little resemblance to clinical effectiveness, ie they allow maximum health gain for patients when resources are finite
- Focus on patients
- Outcomes should always be patient-focused

Slide 15.3

Role for outcome indicators

Public, patients & representing organisations

- local NHS performance
- informed decisions about health and healthcare

Trusts & primary care groups

- quality
- effectiveness
- efficiency
- outcomes of care

Health authorities

- health improvement programmes
- agreements with trusts and primary care groups

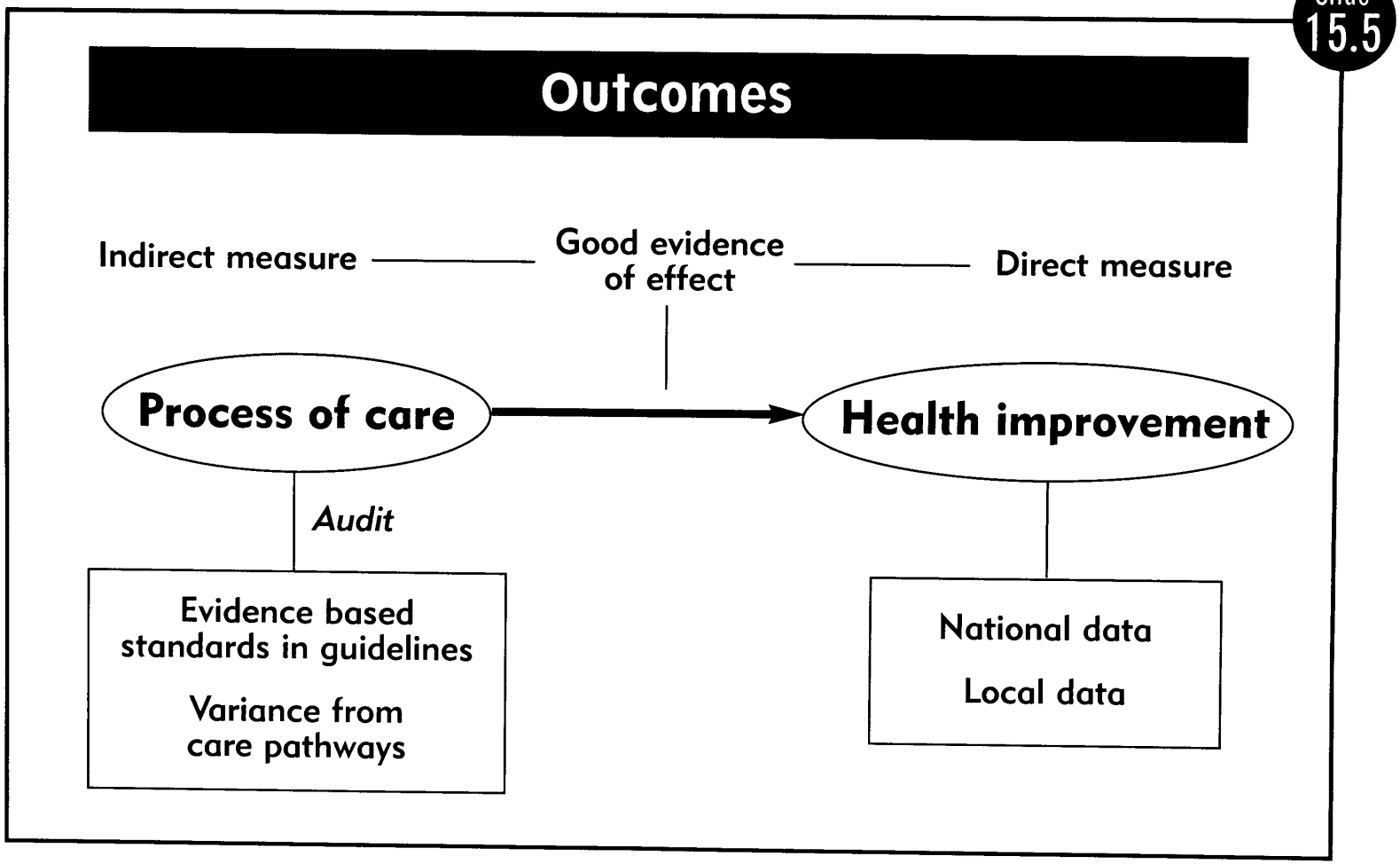
NHS Executive

- performance agreement with health authorities
- developing priorities for NHS
- public accountability for use of NHS resources

Slide 15.4

National focus on outcomes

- **Professionally led confidential inquiries**
  - maternal deaths (since 1952)
  - perioperative deaths
  - suicide & homicide by people with mental illness
  - stillbirths and deaths in infancy
  - counselling for genetic disorders
- **Clinical Outcomes Group**
  - chaired by CMO/CNO
  - remit – quality of clinical care
- **DoH resources supporting outcomes work**
  - Central Health Outcomes Unit
  - UK Clearing House on Health Outcomes



Slide 15.6

Data sources for assessing outcomes

Local

- disease register
- diabetes mellitus
- haemoglobinoathies
- laboratory investigations
- diagnostic imaging
- prescribing data
- patient information systems
- korner returns

National

- public health common dataset
- Health Survey for England
- psychiatric morbidity survey
- dental survey
- confidential enquiries

Local return to national datasets

- communicable disease notifications
- congenital malformations notifications
- prescribing and cost data

Design of outcome studies

- before and after comparisons
- trends over time
- target level achievement
- comparison of groups
  - patients
  - places
- national trends

Slide 15.8

Criteria for clinical indicators

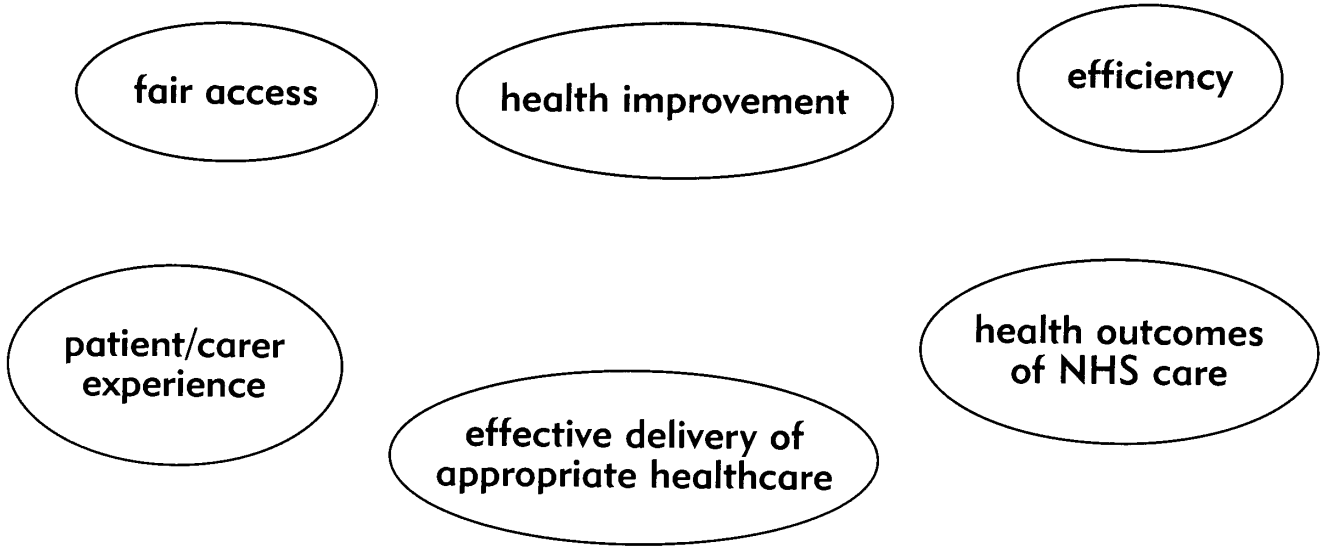
'straightforward measures that are sensitive to the effects of treatment on health'

Hopkins, A. & Costain, D. (Eds) (1990) *Measuring the Outcomes of Medical Care*. London: Royal College of Physicians.

- attributable
- important
- avoid perverse incentives
- robust
- responsive
- data useable and timely

NHS Executive, January 1998

National Performance Framework



NHS Executive, A National Framework for Assessing Performance, January 1998

Slide 15.10

Examples of outcome indicators: 'Saving Lives: Our Healthier Nation'

By the year 2010, to reduce:

- heart disease and stroke death rate in under 75-year-olds by at least a further two-fifths
- death from accidents by at least one-fifth and serious injury by at least one-tenth
- cancer death rate in under 75-year-olds by at least a further one-fifth
- suicide and undetermined injury death rate by at least a further one-fifth

Slide 15.11

National Performance Framework: health outcomes of NHS care

- conception rates in girls aged 13–15
- decayed, missing & filled teeth in 5-year-olds
- avoidable diseases: *pertussis/measles/TB/# proximal femur*
- adverse events/complications of treatment: *28 day emergency readmission/recurrent hernia surgery rates*
- emergency admissions to hospital in >75-year-olds
- emergency psychiatric readmission
- infant deaths including stillbirths
- breast & cervical cancer survival rates
- avoidable deaths: *peptic ulcer/maternal/TB/Hodgkin's disease/ asthma/appendicitis etc*
- in-hospital premature deaths: *30 day mortality perioperatively or post myocardial infarction*

Outcome indicators and the National Performance Framework

Slide 15.12

National performance framework area	Breast cancer outcome indicators
Health improvement	• Standardised mortality ratio
Fair access	• Waiting times • Variation in service take-up
Effective delivery of appropriate healthcare	• Screening coverage • Diagnostic triple assessment, one visit • Trends in stage at diagnosis
Efficiency	• Cost per case detected
Patient/carer experience	• Waiting time to diagnosis • Waiting time diagnosis to operation • Patient satisfaction, complaints
Health outcomes of NHS care	• Cancer registrations • Stage at diagnosis • Avoidable complications • 5 year survival

Initiating change

'It should be borne in mind that there is nothing more difficult to handle, more doubtful of success, and more dangerous to carry through than initiating changes in a state's constitution. The innovator makes enemies of all who prospered under the old order, and only lukewarm support is forthcoming from those who would prosper under the new order.'

Slide 16.2

Steps in project management

1 the mission

2 action plan

3 resources

4 motivation

5 leadership and teamwork

6 progress

Slide 16.3

Making a case

Decide how you would make a case to different people on these issues:

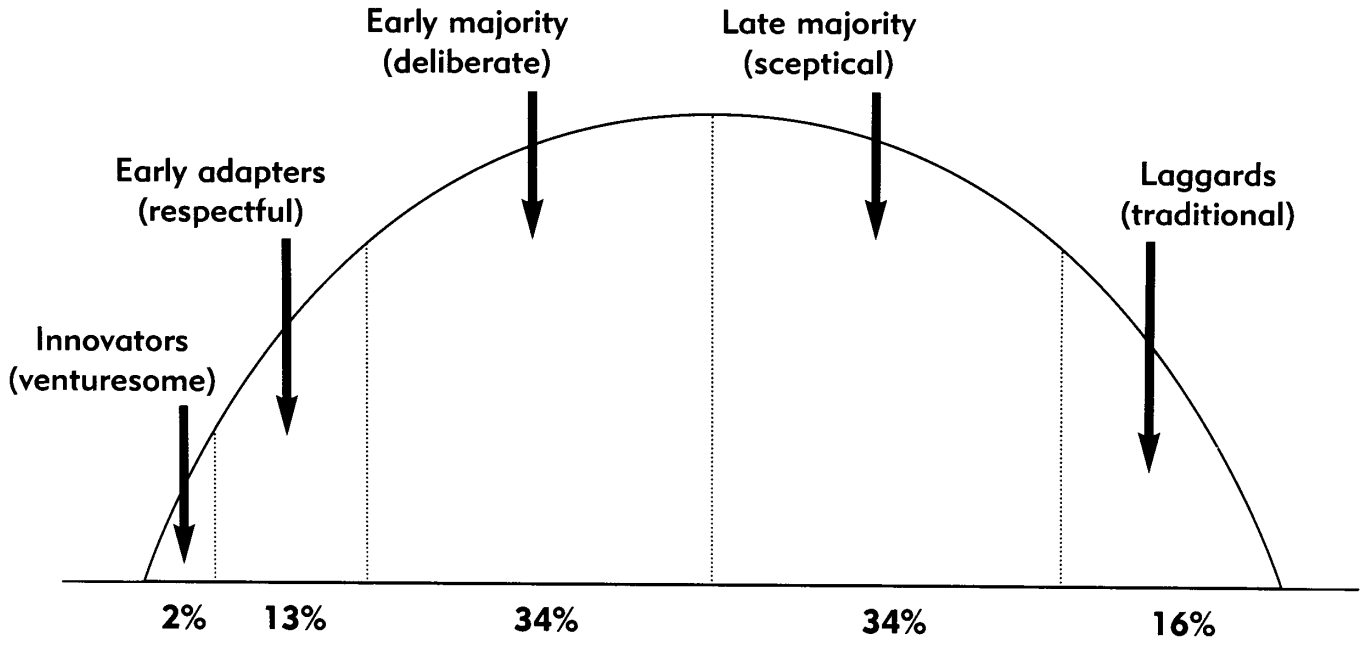
- What is being proposed and why?
- Why is the work important?
- What do you want to be able to do as a result of the project?

Slide 17.1

Planning change

- **Assessment of need**
  Is current practice adequate?
- **Identify resources**
  Force field analysis will help here
- **Plan a strategy**
  You may wish to refer back to project management here
- **Allocating responsibilities**
  Draw on team members' strengths (everyone has something which they are good at. Involvement is one of the best ways of countering resistance)
- **Building in a listening and monitoring process**
- **Baseline data**
  Gather baseline data against which success can be measured
- **Reward success**

The adopter curve



Rogers E. M. (1962) *Diffusion of innovations*. New York: Free Press.

Slide 17.3

Healthcare today

'...never before has common sense been so uncommon'

'Focus on integrating experiences not just structures'

'Learn to use measurement for improvement – not measurement for judgement'

'Develop better ways to learn from each other, not just to discover best practice'

'Reduce total costs, not just local costs'

'Compete against disease, not against each other'

Berwick, D. (1996) Quality Comes Home. *Annals of Internal Medicine* **15** Nov.

Of people who have gained emancipation:

'...they let go of their present conceptions of how to solve problems...once they let go they have the capacity to come up with brave solutions that integrate all the information.'

[redacted]