

WHO PROGRAMME TO MAP BEST REPRODUCTIVE HEALTH PRACTICES

# Making evidence-based decisions in reproductive health: a training course

FACILITATOR MANUAL



World Health  
Organization



THE COCHRANE  
COLLABORATION®



The statue on the cover page is from the private collection of Dr Vincent Fauveau, Senior Maternal Health Advisor, United Nations Population Fund (UNFPA)

# **MAKING EVIDENCE-BASED DECISIONS IN REPRODUCTIVE HEALTH: A training course**

This document was initially developed by the South African Cochrane Centre (Medical Research Council, Cape Town, South Africa) and revised by Ms Lindeka Mangesi (Effective Care Research Unit, University of the Witwatersrand and Fort Hare, East London, South Africa), Regina Kulier (Geneva Foundation for Medical Education and Research, Geneva, Switzerland), Oluwole Akande (Ibadan University, Ibadan, Nigeria) and A. Metin Gülmezoglu (World Health Organization, Geneva, Switzerland) in November 2004. We thank Ms Jane Cottingham and Dr Carlos Huezo for their helpful comments. The WHO Regional Office for Africa has supported the development of course materials and actively participated in the workshops.

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## Abbreviations and acronyms in this manual

<b>CC</b>	Cochrane Collaboration
<b>CCT</b>	Controlled clinical trial
<b>CCTR</b>	Cochrane Controlled Trials Register
<b>CI</b>	Confidence interval
<b>CL</b>	The Cochrane Library
<b>CD-ROM</b>	Compact Disc - Read Only Memory
<b>CDSR</b>	Cochrane Database of Systematic Reviews
<b>DARE</b>	Database of Abstracts of Reviews of Effectiveness
<b>EBHC</b>	Evidence-based health care
<b>EMBASE</b>	Excerpta Medica database
<b>MEDLINE</b>	U.S. National Library of Medicine
<b>MeSH</b>	Medical Subject Headings
<b>MMR</b>	Maternal mortality ratio
<b>NNT</b>	Number needed to treat
<b>OR</b>	Odds ratio
<b>P-VALUE</b>	The probability
<b>RCT</b>	Randomised controlled trial
<b>RD</b>	Risk difference
<b>RHL</b>	The WHO Reproductive Health Library
<b>RHR</b>	Reproductive Health and Research
<b>RR</b>	Relative risk
<b>SACC</b>	South African Cochrane Centre
<b>WHO</b>	The World Health Organization

## Foreword

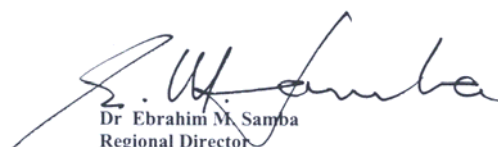
A lot has been achieved in improving health indicators in the various health programmes in the African Region. However, some major obstacles in the implementation of health programmes in general and the reproductive health programme in particular still exist. These include: health professionals' attitudes and resistance to change; poor performance of health systems and unsatisfactory working conditions in health facilities; imbalance in the distribution of health personnel between urban and rural areas; the brain drain due mainly to inadequate remuneration and lack of professional progression; frequent occurrence of conflicts and wars, as well as poverty.

Although much has been achieved over the past two decades in the area of reproductive health in Africa, maternal and neonatal deaths still remain very high. The maternal mortality ratio (MMR) averages 1,000 deaths per 100,000 live births. One of the goals set for the "Health-for-All Policy in the 21st Century in the African Region: Agenda 2020" is to reduce the MMR by 50% of its current level. One of the Millennium Development Goals is also to ensure that all women have access to skilled attendants throughout pregnancy, child-birth and the post-partum period.

Throughout their life cycle, women suffer more than men do from a large number of health problems. Pregnancy and child-birth are accompanied by immense risks, resulting in countries in the African Region having the highest MMR in the world. A woman in Africa has a 1 in 16 chance of dying in child-birth as compared to around 1 in 4,000 in Europe. In countries facing complex emergencies like civil conflicts, maternal mortality is especially high. It is estimated that 272,000 women die annually from child-birth-related causes in Africa. The major cause of these deaths is lack of access to health care, which is exacerbated by poverty, illiteracy and the social and economic inequality of women. Female genital mutilation continues to be practiced in 27 out of the 46 Member States, while the increase in domestic violence and sexual abuse against women and the girl child is of serious concern.

Little progress has been made in the reduction of perinatal and neonatal mortality rates, which range between 35 and 111 per 1,000 births and 40 and 56 per 1,000 live births respectively. The gains made in the area of child health have been grossly affected by the HIV / AIDS epidemic which, in most countries, is on the rise. HIV /AIDS is a major threat to the health systems in the Region because of the enormous demands it makes for health care as well as the loss of health personnel due to the pandemic.

Many health workers and policy-makers in the African Region do not have easy access to the most recent and reliable information on effective care and decisions are often taken without relevant evidence due to inadequate research and non-dissemination and non-utilization of research findings where they are available. One of the major new areas of emphasis in the "Strategic Framework 2002-2005: The work of WHO in the African Region" will, therefore, be promotion of research and making evidence available for policy making and health management. The implementation of the Evidence-Based Reproductive Health Care Initiative should, therefore, strengthen the capacity of health workers and improve the quality of reproductive health care for all peoples in African Region.



Dr. Ebrahim M. Samba  
Regional Director

The World Health Organization





## Introduction

This training Initiative, developed by the Regional Office of the World Health Organization in Africa (WHO/AFRO) together with the WHO Department of Reproductive Health and Research in Geneva (WHO/RHR), is aimed at building the capacity of health workers and policy-makers in the utilization of evidence-based reproductive health practices in resource-constrained settings. The use of current best available evidence from relevant, valid research about the effects of different forms of health care in making decisions about the management and care of individual patients or the delivery of health services is crucial in settings where resources are limited.

A Regional Consultation was held with experts in reproductive health from six countries in the African region (Cameroon, Ethiopia, Mozambique, Nigeria, Uganda and Zambia), the staff of the South African Cochrane Centre and WHO in Cape Town in February 2001. Subsequently, WHO commissioned the South African Cochrane Centre (SACC) to produce a Training Package in consultation with experts and the WHO Secretariat.

### **The Training Initiative is aimed at:**

1. Raising awareness about the benefits of evidence-based decision-making to improve reproductive health practices.
2. Familiarize reproductive health workers with the principles of evidence-based decision-making.
3. Equip reproductive health workers with the basic knowledge and necessary tools to improve reproductive health care practices.
4. Establishing support mechanisms for expanding evidence-based decision-making in the African region.
5. Creating a critical mass of health workers who can train others locally.

The training package has been designed to be flexible and adaptable enough to be used by all cadres of reproductive health professionals since in practice there is an overlap in the roles and responsibilities of these cadres of workers. This package also includes appropriate tools and indicators for monitoring and evaluation that are regarded as essential features of the initiative.

Evaluation of the training package during the initial pilot workshops have greatly assisted the developmental process and improved the quality of the final product.

It is hoped that this Initiative will prove to be of considerable benefit in building appropriate capacity in the African Region in the utilization of up-to-date information based on systematically synthesized evidence in reproductive health care.

Professor E. Oluwole Akande, Consultant





## Structure of the course

Making evidence-based decisions in reproductive health is a modular course aiming to increase the knowledge and skills about using research evidence. This manual aims to assist the facilitators in organizing, implementing and monitoring the courses.

This is a three and a half day course in the form of presentations, case studies, group work and aims to be interactive. The sessions are arranged in 'modules' so that the timing and flow can be changed if the facilitators feel that they need to make modifications depending on the profile of the participants or available time. Those who are familiar with the programme can use the modules independently for other training activities. This document should be used with the PowerPoint slides provided at the end of this manual.

The contents are flexible and they are revised in the light of evaluations of the workshops annually.

**Day 1:** Day one focuses on creating an atmosphere conducive to learning and active participation and provides introduction to Evidence Based Health Care and all the related theories, incl. study designs, meta-analysis, introduction to *The Cochrane Library* and *The WHO Reproductive Health Library*.

**Day 2:** Day two leads to the development of skills to assess research studies and reviews for their quality (critical appraisal). Role plays to evaluate the knowledge gained and practical hands on session also form part of day two.

**Day 3:** Day three focuses on the challenges to implementation of interventions of proven effectiveness and aims to develop skills in dealing with those challenges. Part of day 3 is in the form of group work with participants finding answers in RHL and using research to evaluate current practices. A board game is played at the end of day 3 to evaluate what participants have learnt. Participants are given homework to identify challenges in their settings and possible solutions. This can be done as group work and then presented on day 4.

**Day 4:** On day 4 there is a session on possible implementation strategies and a question and answer session. The workshop is evaluated and plans for future activities will be discussed.

At the end of each day there is a short summary (reflections) about the key points of the day. The programme indicated in three and a half days is for guidance only. Depending on the availability of time and venue the start and end times can be modified. Two coffee/tea breaks and one lunch break are anticipated. These should be timed according to local customs.

## Programme

<b>Day 1</b>	<b>Topic</b>	<b>Time</b>
Module 1	Welcome and introduction (2 parts)	Morning
Module 2	Formulating and solving a clinical question	Morning
Module 3	Study designs and bias	Afternoon
Module 4	Searching for evidence: Cochrane Library and RHL	Afternoon
<b>Day 2</b>		
Module 5	Measures of effect	Morning
Module 6	RHL practical	Morning
Module 7	Evaluating research reports	Afternoon
<b>Day 3</b>		
Module 8	Health care challenges	Morning
Module 9	Example of an implementation strategy	Morning
Module 10	Case study: prophylactic corticosteroids for preterm birth	Morning
Module 11	Myths and episiotomies	Afternoon
Module 12	Board game	Afternoon
<b>Day 4</b>		
Module 13	Revisions and implementing EBHC	Morning

## Who are the facilitators?

The workshop is designed with the intention of disseminating and implementing evidence-based reproductive health care. It is often not easy to facilitate a workshop after attending one. Individuals need to have experience in the field, exposure to the course beforehand and aware of some techniques in facilitating courses. For the purposes of this course the following characteristics are important:

1. Working in the reproductive health field (clinically or policy formulating level)
2. Has good understanding of English
3. Is willing to work in a team
4. Has basic computer understanding
5. Is willing to disseminate the acquired skills and knowledge to a wider professional and academic audience
6. Is organized and can plan ahead!

Facilitators are equipped with the facilitator manual (this document), which should be studied beforehand so that any areas that need clarification can be addressed before the course starts.

## Getting organized

It is often good practice to have a checklist for preparatory activities so that all details are thought through. A large amount of organization and administration is required prior to running the course. Depending on the funding source or the sponsor the organizational aspects could involve arranging everything from the venue and catering to liaising with the relevant government and university departments to ensure that participants are released from their daily duties to attend the workshop. Once the funding is secured the most important step is to clarify the roles and responsibilities of various parties involved.

It is useful to keep a checklist of all organizational tasks and the responsible people so that all tasks are completed and can be monitored.

Capturing the details of each participant attending the workshop using a registration form that participants complete prior to attending is also useful. Important information to capture about each participant will include their professional designation, their place of work, and their contact details (for follow-up after the workshop).

### Equipment

Make sure that you have everything that you will need. Keep the list of your daily requirements handy. Check before the participants arrive to see if everything is in working order. If you are using PowerPoint presentations, put your computer on and sit on the chair in the last row and see if your slides are visible. Find out where the switches for the lights are in case you need to switch them on and off during the presentation.

### Punctuality

It is important to always arrive at least 30 minutes before the beginning of the session.

**Depending on how formal the event is and the number of participants you may need the following:**

#### **Day 1**

- Name tags
- Paper name stands to put on the desks in front of the participants
- Manuals
- Pens and paper
- Computer and a projector together with all connections
- Disc with your PowerPoint presentation
- White board and white board markers
- Flip charts and markers
- Glue to stick the question papers on the wall
- Tools for an ice breaker

**Day 2:**

- Computers for a practical session
- Computer with projector together with all connections
- Disc with your PowerPoint presentation
- White board and white board markers
- Flip charts and markers

**Day 3:**

- Computers for a practical session
- Computer with projector together with all connections
- Disc with your PowerPoint presentation
- White board and white board markers
- Flip charts and markers
- Board games

**Day 4:**

- Computer and all accessories that have been used to prepare the answers
- White board and marker
- Questions that were stuck by participants on the wall
- Questions that were missed during the board game

## What makes workshops/courses work?

Training courses are an ideal opportunity for engaging professionals in active learning and teaching. Participants are provided the opportunity for mental and physical involvement with information and skills which have personal and professional significance. When training is active, it invites participants to use their existing knowledge and skills in reflection, solving problems and critical thinking. Active training places participants and trainers in a personally engaging, supportive, exciting and valuable interactive process in which everyone learns, and everyone teaches. Training professionals is a rich experience. They have diverse, interesting, complex and sometimes painful experiences which prepare them for further experiences of a deeper quality.

Not all people respond to similar messages in similar ways. Audiences have diverse information needs. Hence the training needs to be varied. Some participatory experiential learning/teaching techniques include games, simulations, group discussion, critical incidents, role-play, lectures and demonstrations.

A training course needs to take into account the context in which participants practice. When knowledge and skills are relevant to the setting in which it will be applied, the outcome is generally positive. There is significant variance in infrastructure, resources, knowledge and skills in health care. It is a worthwhile exercise to find out about the health districts and health facilities from which participants are drawn. Flexibility is crucial, and the trainer will have to attend to complex issues such as access to technology and differing

understandings of health care needs. One approach to addressing the question of diversity is to create opportunities for discussing diversity and generating creative approaches for dealing with it.

### Approaches to learning and teaching

Approaches to learning are wide and varied. People perceive and receive information in different ways and individual learning styles vary from one subject to another, and from one learning environment to another. The “Information Highway” has led to a situation in which people are bombarded with information and most times only a fraction is selected and stored in working memory. It might be useful for you as a facilitator to review some of the ways in which people learn.

Information that enters *via the senses*, i.e. sights, sounds and physical sensations are preferred by those who like to solve problems using well-established procedures, who can cope with details and who do not like unexpected complications.

*Intuitive learners* enjoy learning that arises internally through memory, reflection and imagination. People who learn in this way seek variety in their work, do not mind complexity and become disinterested with too much repetition.

Pictures, diagrams, graphs, schema and demonstrations are found to be stimulating to visual learners.

*Verbal learners* respond favorably to written and spoken words and mathematical formulae. There is yet another type of learning to consider.

*Inductive learners* choose to learn new material through observations, experimental results, numerical examples from which they work towards understanding governing principles and theories by inference. People who learn in this way prefer less structure.

*Deductive learners* start with general principles and deduce consequences and applications. They tend to like highly structured presentations.

*Active learners* benefit most when they are doing something active, while reflective learners think things through quietly before applying them.

Then there are those who take in information in fragments and achieve learning in large, holistic leaps. *Sequential learners* develop understanding in small, connected pieces.

The use of a wide range of creative instructional methods can do much to develop an interest in the subject and relieve boredom. By varying tasks and exercises, participants are less likely to feel that they are not benefiting from the training. The nature of interest, previous knowledge and a sense of ownership of the material influence the way in which meaning and structure is attributed to the material. Trainers can do much to engage their audience. It is believed that the audience shows a deeper interest and involvement with the subject when the trainer communicates his/her own interest and passion for the subject.

### Tips for facilitators

#### Introductions

The workshop introduction has the potential to get participants active right from the start. The introductory activity should set a non-threatening, comfortable atmosphere, build teamwork and immediately start people thinking about the subject matter. In this course we have a

game called the reproductive health word game. Participants are given a word, pasted on their backs, and through a question and clue process they have to arrive at their word. Other examples for getting started are:

- Personalised name-tags can be brightened by providing stickers, animals, a zodiac sign or any pictures which symbolise a personal quality.
- Participants introduce themselves by sharing the origin of their name or who they were named after.
- Name-tag-search: mix up the name tags and get participants to choose someone else's name. Participants circulate until they can "tag" the owner.

### Eliciting participant expectations

There are many ways to explore the expectations, needs and concerns of participants. This is useful for clarifying the purpose of the training session and allows for adjustment so that sessions can be steered in the appropriate direction. Some opening questions to consider:

- Name one thing you want to take away from this workshop.
- What knowledge and skills are you seeking?
- What are your hopes and/or concerns of this training?
- What brought you here?

### Ice breakers

Ice breakers aim at creating a relaxed and trusting environment where participants can relate to each other without any tension. This promotes cooperation especially if the workshop is designed to be of a participative nature.



### **STARTUP ICE BREAKER:**

This ice breaker also serves another purpose in the workshop: (Finding the expectations of the participants)

Have pieces of paper, same number as the participants. Write different instructions in the papers and fold them. The instructions may be: find anyone in the group who is wearing spectacles, find anyone who likes to eat meat, find anyone who is single, find anyone who is talkative, anyone who has two kids, etc. The papers must be placed in a box, a basin or a hat and the participants must be asked to take one piece. The participants should find the people as instructed and ask them to give at least one expectation that they have from the workshop.

After they have finished, the facilitator will call out one participant from the list and ask him/her to report on the name of his/her partner (using the preferred one on the name stand), what the instruction was and to report on what s/he has for the group. When s/he finishes, s/he picks up the participant from the group and calls him/her by the name that is written on his/her desk to come and do the same. This then continues until everyone has presented or until the allotted time has elapsed. If time will not allow for everyone to present, please condition participants before that they may not all present.

At the time of presentations the facilitator will be writing the stated expectations and will use them to see if the participants' expectations have been met.

### **ICE BREAKER:**

Cultural practices that impact on health care scattered around the world there is a treasure chest of knowledge about conception, pregnancy, birth and the care of babies. It is not often that we get the opportunity to share these experiences and sadly, much of this knowledge is lost to those of us who dedicate our lives to reproductive health. In this session rests the opportunity to visit those practices and rituals which are passed from generation to generation and which persist and continue to operate along with advances in technology and science. Here are some stories which might stimulate your curiosity about pregnancy and birth rituals in your setting.

#### **Conception**

Among the Malay people, the baby is believed to begin life in the father's brain. The fetus develops there for 40 days before descending into the father's penis. During lovemaking it is ejected into the mother's womb where it is nourished and nurtured until birth.

In other situations, no link is made between sexual intercourse and conception. In South Africa there are some women who believe that all they need to do is to lay down in a delicious shower of cool rain and their seed will come alive, to grow into a beautiful baby.

#### **Gender**

In many cultures the sex of the baby is extremely important and the older women are often consulted to make an accurate prediction.

The shape of the abdomen is often said to be the tell-tale sign. A low-slung pregnancy is believed to be a boy, while a pointed, high pregnant belly holds a girl.

Superstitions in Europe that have emerged from the Ancient Greeks claim that girls develop in the left side of the womb where it is cooler, and boys in the warmer right side.

### **Emotions**

In the Western world it is believed that her unborn fetus experiences the mother's emotions. In birth preparation classes women are encouraged to be calm and to listen to gentle, soothing music.

Mexican Indians warn that a mother's anxiety, which causes knots in the stomach, will form knots in the umbilical cord.

### **Food**

In some Indian cultures it is believed that hot food will make the baby hot-tempered.

### **Birth**

A Zulu tradition holds that it is very important for the baby to see a thing of beauty when it arrives in the world. They hang colored beads and carvings around the birthing room. One wonders then about the austere, sterile rooms of hospitals into which modern babies are born!

Music is used by Navaho Indians to help women in labour to tune into the rhythm of the contractions.

## **Energizers**

Energizers may or may not be necessary. It depends on how heavy the workshop is. Some sessions are more heavy and tiring and you may notice that participants are tired and find it difficult to concentrate. Energizers can help you recharge your participants.

### **SAMPLE ENERGIZER:**

Inform the participants on the left hand side that in this energizer they are males and those on the right hand side are females. Tell them that they will sing a song with you. Tell females (those on the right side) that they will have to stand up every time the word with 'F' is mentioned and that they will have to sit down every time the word with 'M' is mentioned. Males (those on the left side) will have to stand up every time the word with 'M' is mentioned and sit down every time the word with 'F' is mentioned. The one who makes a mistake will have to come to the front and write his/her name using his/ her body without moving his/her feet. The song goes like:

"I will make you fishers of men, fishers of men, fishers of men. I will make you fishers of men if you follow me. If you follow me, if you follow me, I will make you fishers of men if you follow me".

## Presentations

Check if your equipment is working before the beginning of the session. If for any reason there is a technical problem, explain this to participants and apologize. Your voice must be audible. Have a pointer ready if you will use it (optional). Your back must never face the audience. It is not wise to give participants hand outs in the middle of the presentation as the focus will be on the hand outs and not on the presentation. This, you can only do if you will put the presentation on hold and allow participants time to look on the hand outs. Do not be ashamed to say “I will probably give you an answer before the end of the day” if you are asked a question you are not sure how to answer.

## Group work

Group work can be stimulating. It is important to find an efficient grouping strategy as much time can be spent organizing an audience into groups. Here are some options for group-formation:

- Calendar months
- Seasons
- Use a deck of playing cards and vary group formations as required

Allow the group to choose their own chairperson and rapporteur. You will notice that groups are able to organize themselves quickly into subgroups in relation to their own special talents. Do allow as much space as possible for the group to establish and define themselves. It may be necessary to spend some time with each individual group to make sure that they are sticking to the plan, that they understand what the outcome of the group work should be and that they are not side-tracked into a different discussion.

## Case study

In case studies are case scenarios which are used with an intention of learning something from them. These sessions will usually take place in a group format. The group will have to solve problems related to that case. The case study should be read clearly as there are questions that usually follow. The facilitator may ask for a volunteer from the participants to read a case study from their manuals or he/she may do this herself.

## Role play

Role-playing is fun, safe and gives participants the opportunity to act out and reflect on their life and work experiences. It has proved to be an effective technique for eliciting participation and involvement. It allows for the creation of a risk-free environment in which real-life situations can be acted out with sufficient objectivity and involvement to make it a rich learning experience. Role-playing can be presented in a wide variety of formats and has a tendency to evolve spontaneously as participants release their creativity.

### **Spontaneous role-play**

Spontaneous role-playing develops when group members discuss their challenges and a common problem recurs. This provides the opportunity for the facilitator to ask volunteers to act out the situation. Feelings, tensions and frustrations can be expressed without inhibition. The group is then given the opportunity to critique the situation and brain-storm possible solutions. The facilitator prompts the group to explore what was learned, which opportunities

were missed and which behaviours could be improved. This type of role-play works well since it is based on personal experience and has application in their lives.

### **The demonstration-type role-play**

Demonstration-type role-plays are acted out before the rest of the participants as a skit presented by two or more role-players. The instructions are provided by the facilitator and it usually illustrates a problem or demonstrates a particular skill. A written script may be used so that the players make the points or present the problem accurately. Remember to give the players enough time to prepare for their role! After the role-play the opinions of the participants can be elicited by means of a general discussion. The facilitator can summarise the main points and what was learnt from the role-play.

### **Group role-playing**

The number of participants in a role-play need not be limited. When the learning involves group processes in work situations, the players can be selected to represent all relevant group members. Role players can be given different instruction sheets to follow. Observers can be appointed to record “task” roles such as initiator, objector, etc and “group maintenance” roles like support, encouragement, morale, etc. The appointed observers report their observations before the group discusses the interaction.

Another variation is to break all participants up into role-playing groups so that everyone gets to play.

### **Practical sessions**

Practical sessions aim at equipping participants with the necessary skills that they will independently use after the work shop. It is important to remember that some participants have better understanding of a programme than others. They will therefore have a tendency of viewing areas that the facilitator has not covered yet. This may result in a loss of control as they may ask questions in areas that have not been reached yet. It is always wise to request participants to follow the same pace with the facilitators before the practical session is commenced. For example, few minutes may be taken to introduce participants to the contents of the library, to practice the search process before going to the systematic review that has been selected to practice RHL. This is because if participants are not sure about searching they will practice searching whilst you are busy with the systematic review as an example for a practical session.

### **Games**

The game in the EBHC workshop is the board game. It is educative and brings about lots of excitements as it is also entertaining. It is a game played with a dice and token with questions to answer on cards. There should be one referee per game and the referees are usually the facilitators. They must have their pens ready to write the questions that were missed by participants. Reassure the participants that the referees will be writing the questions for further clarity not people who have missed the questions. These questions will then be addressed later.

### **Reflections**

The facilitator reflects on what was done during the day. S/he highlights only important areas in each of the sessions.

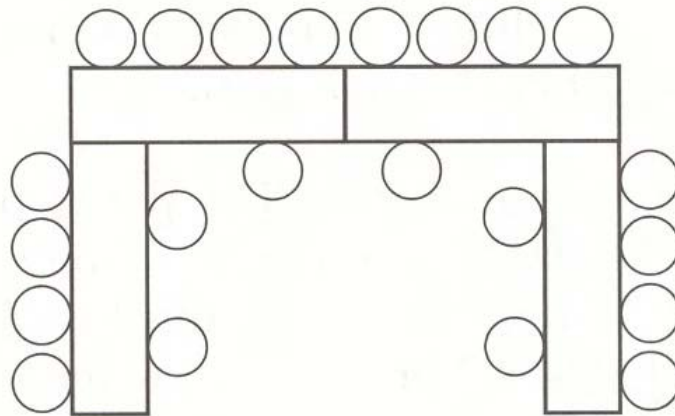
## Preparing the training room

Some important principles to remember when preparing the training room:

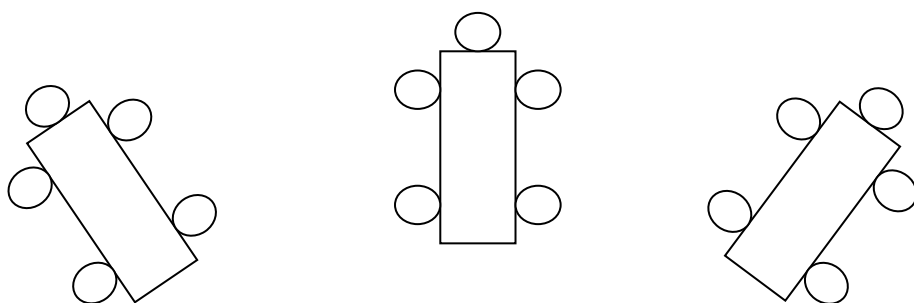
- Participants need a reading and writing surface
- Everyone should be able to see the trainer easily
- All visual aids should be visible to everyone

## Setting up the training room

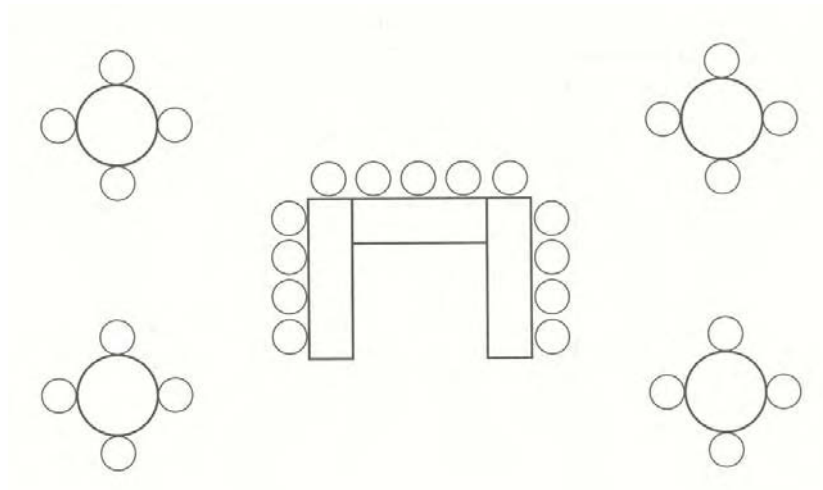
Rooms are usually standard square or rectangular in shape. Furniture can be arranged to match the intention of the training activities. Here are some examples. Seating should make face-to-face contact, pairing or grouping possible.



**The horseshoe arrangement works well with rectangular tables.**



**Grouping rectangular or circular tables around the room enables the facilitator to have every participant in his/her line of vision.**



**This arrangement facilitates group or team-based activities**

## Monitoring and Evaluation

The monitoring of organizational tasks related to the course is described earlier. If you are initiating a programme of a series of courses it will be important to have a plan to monitor their implementation according to the plan and to identify any problems that emerge.

The evaluation of the course has two objectives. First, to evaluate the participant responses in terms of the running of the course, the materials and the sessions and second, in terms of the knowledge before the course and gained during and after the course.

### **The objectives of the course are:**

- To effectively use tools such as the *WHO Reproductive Health Library* and the *Cochrane Library*
- To critically appraise clinical evidence for its validity and applicability
- To understand basic measures of efficacy such as relative risk and number needed to treat
- To plan for using evidence for formulating policy and practice

### **Daily Evaluation Forms**

Each day participants are asked to complete an evaluation form for each session of the programme. The questions relate to:

- Learning objectives
- Presentation quality
- The 'enjoyment' factor

It is easier to analyse a questionnaire that forces participants to choose one option for each question. This provides us with quantitative data about the sessions. However, important information is often lost so it is essential to provide space for participants to provide an assessment in their own words. This will provide qualitative data.

### **Reflections**

At the end of each day, the programme includes a period of 15 minutes called 'reflections'. This time is included so that participants can ask any outstanding questions and give the facilitators feedback about the day. It is a good idea to write down what participants say in these sessions as very often it can provide excellent qualitative information about the workshop that is not adequately captured in the evaluation forms.

### **Pre and post course surveys**

There are different ways of evaluating the knowledge and attitudes of participants and how much they benefit from the course eventually. It is important to keep these evaluations simple and easy to complete. If the evaluations are too cumbersome it will affect the response rates and the attention people show for completing the survey questionnaires. We include one

survey questionnaire below that can be used both before and after the course. You can print the survey from this manual directly or modify according to your particular needs and circumstances. Participants often feel more comfortable if the surveys are conducted anonymously.



## Knowledge questionnaire for participants

We would be grateful if you would take the time to complete the brief questionnaire below. You can choose to remain anonymous and all responses will be treated as confidential. We look forward to hearing from you.

Should you have any questions, please do not hesitate to contact the course facilitator. Please put a cross in the appropriate box.

**1. Are you?**

Male

Female

**2. Are you?**

30 years or less

31 - 40 years old

41 - 50 years old

> 50 years old

**3. What is your professional designation?**

Midwife

Labour ward assistant

Obstetrician

Policy-maker / programme manager

Other - please specify .....

**4. Is your work setting mainly**

Rural

Urban

Mixed

**5. Do you work?**

Full-time

Part-time

**6. How many years experience in reproductive health care do you have?**

Less than 2 years

2 - 5 years

5 - 10 years

More than 10 years

**7. Where do you have access to a computer?**

- I do not have access to a computer
- Only at work
- Only at home
- Both at work and at home

**8. Have you heard about RHL (The WHO Reproductive Health Library)?**

- No
- Yes

**9. If you have access to RHL how often do you use it?**

- I do not use it.
- Rarely
- A few times a month
- Weekly

**10. Do you find the information you need in RHL?**

- Never
- Rarely
- Sometimes
- Most of the time

**11. Have you ever attended a course related to evidence-based health care?**

- No
- Yes - if so, which one .....

**12. Where do you have access to the World Wide Web (internet)?**

- I do not have access to the World Wide Web
- Only at work
- Only at home
- Both at work and at home

13. There are a growing number of journals, review publications and databases relevant to evidence-based reproductive health care - please indicate those you use or are aware of:

	Unaware	Aware but not used	Read or use	Helps me in my clinical decision-making
MEDLINE/PUBMED				
Clinical Evidence ( <i>book</i> )				
The WHO Reproductive Health Library				
The Cochrane Library				
Other: Specify .....				

14. The following terms are often used when evidence-based reproductive health care is mentioned- please indicate your reaction to them by ticking the appropriate box:

	Never heard	Heard but don't know the meaning	I know what it means	Can interpret and explain to others
Relative risk				
Confidence intervals				
Randomised controlled trial				
Systematic review				
Number needed to treat				

15. Please state whether the following statements are true, false or you do not know:

	True	False	Don't know
Antenatal steroids are not effective for the prevention of respiratory distress syndrome.			
Magnesium sulphate is the anti-convulsant of choice for women with eclampsia.			
Caregiver support during labour is detrimental to the mother.			

**16. Please tick the boxes that best express your thoughts about the following:**

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Practicing evidence-based reproductive health care improves patient care					
Practicing evidence-based reproductive health care will overload me even more than I already am					
Evidence-based guidelines for managing labour are too simplistic					
Research findings are useful in my day to day practice					
Most obstetricians do not have the skills to practice evidence-based reproductive health care					
Most midwives do not have the skills to practice evidence-based reproductive health care					
It is not possible to assess the effectiveness of many obstetric interventions					

**17. If training in evidence-based reproductive health were offered, how much time could you spend attending a course?**

- I would not attend training
- Half-day workshop
- 1-day workshop
- Sessions one night a week for five weeks

**18. Any other comments? Feel free to use the back of this page.**

.....

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## Daily evaluation

DAY.....DATE.....

Please ✓ a box that best describes your thoughts for each session.

TOPIC:.....					
<i>The session was</i>	Very good	Good	Moderate	Slightly poor	Poor
<i>The content was</i>	Very clear	Clear	Moderately clear	Slightly unclear	Unclear
<i>I learnt</i>	A great deal	Quite a deal	A moderate amount	Only a little	Almost nothing

TOPIC:.....					
<i>The session was</i>	Very good	Good	Moderate	Slightly poor	Poor
<i>The content was</i>	Very Useful	Useful	Moderately useful	Slightly useful	Not useful
<i>I learnt</i>	A great deal	Quite a deal	A moderate amount	Only a little	Almost nothing

TOPIC:.....					
<i>The session was</i>	Very good	Good	Moderate	Slightly poor	Poor
<i>The content was</i>	Very Useful	Useful	Moderately useful	Slightly useful	Not useful
<i>I learnt</i>	A great deal	Quite a deal	A moderate amount	Only a little	Almost nothing

TOPIC:.....					
<i>The session was</i>	Very good	Good	Moderate	Slightly poor	Poor
<i>The content was</i>	Very Useful	Useful	Moderately useful	Slightly useful	Not useful
<i>I learnt</i>	A great deal	Quite a deal	A moderate amount	Only a little	Almost nothing

TOPIC:.....					
<i>The session_ was</i>	Very good	Good	Moderate	Slightly poor	Poor
<i>The content was</i>	Very clear	Clear	Moderately clear	Slightly unclear	Unclear
<i>I learnt</i>	A great deal	Quite a deal	A moderate amount	Only a little	Almost nothing

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<i>The content was</i>	Very clear	Clear	Moderately clear	Slightly unclear	Unclear
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<i>The session_ was</i>	Very good	Good	Moderate	Slightly poor	Poor
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	clear		clear	unclear	
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*Please use space provided for additional comments or suggestions*



## Glossary of terms

### **Allocation concealment**

See concealment of allocation.

### **Attrition bias**

Systematic differences between comparison groups in withdrawals or exclusions of participants from the results of a study. For example, patients may drop out of a study because of side-effects of the intervention. Excluding these patients from the analysis could result in an overestimate of the effectiveness of the intervention.

### **Bias**

Systematic error or deviation in results or inferences. In studies of the effects of health care bias can arise from systematic differences in the groups that are compared (selection bias), the care that is provided, or exposure to other factors apart from the intervention of interest (performance bias), withdrawals or exclusions of people entered into the study (attrition bias) or how outcomes are assessed (detection bias). Bias does not necessarily carry an imputation of prejudice, such as the investigators' desire for particular results. This differs from conventional use of the word in which bias refers to a partisan point of view. Many varieties of biases have been described. See also methodological quality, validity.

### **Blinding (synonym: masking)**

Keeping group assignment (e.g. to treatment or control) secret from the study participants or investigators. Blinding is used to protect against the possibility that knowledge of assignment may affect patient response to treatment, provider behaviours (performance bias) or outcome assessment (detection bias). Blinding is not always practical (e.g. when comparing surgery to drug treatment). The importance of blinding depends on how objective the outcome measure is; blinding is more important for less objective outcome measures such as pain or quality of life. See also single blind, double blind and triple blind.

### **Case study (synonyms: anecdote, case history, single case report)**

An uncontrolled observational study involving an intervention and outcome for a single person.

### **Case-control study (synonyms: case referent study, retrospective study)**

A study that starts with the identification of people with the disease or outcome of interest (cases) and a suitable control group without the disease or outcome. The relationship of an attribute (intervention, exposure or risk factor) to the outcome of interest is examined by comparing the frequency or level of the attribute in the cases and controls. For example, to determine whether thalidomide caused birth defects a group of children with birth defects (cases) could be compared to a group of children without birth defects (controls). The groups would then be compared with respect to the proportion exposed to thalidomide through their mothers taking the tablets. Case-control studies are sometimes described as being retrospective studies as they are always performed looking back in time.

### **CD-ROM (Compact Disc – Read Only Memory)**

A computer storage medium. A CD-ROM can contain a database of information (e.g. MEDLINE, or the Cochrane Controlled Trials Register) that may be searched either on a personal computer or a computer linked to a network.

## **CDSR**

See Cochrane Database of Systematic Reviews.

## **CL**

See Cochrane Library

## **Clinical trial (synonyms: therapeutic trial, intervention study)**

A trial that tests out a drug or other intervention to assess its effectiveness and safety. This general term encompasses randomised-controlled trials and controlled clinical trials.

## **Cochrane Collaboration**

An international organisation that aims to help people make well-informed decisions about health by preparing, maintaining and ensuring the accessibility of systematic reviews of the benefits and risks of health care interventions. More information on the Cochrane Collaboration is available from the Cochrane Library.

## **Cochrane Controlled Trials Register (CCTR)**

A database of references to controlled trials in health care. Cochrane groups and other organisations have been invited to contribute their specialised registers, and these registers, together with references to clinical trials identified on MEDLINE, form the CENTRAL register of studies. Records from CENTRAL, following quality control to try to ensure that only reports of definite randomised controlled trials or controlled clinical trials are included, make up The Cochrane Controlled Trials Register (CCTR).

## **Cochrane Database of Systematic Reviews (CDSR)**

The major product of the Cochrane Collaboration. It brings together all the currently available Cochrane Reviews and is updated quarterly. It also contains information about the Collaboration. See Cochrane Library.

## **Cochrane Library (CL)**

A collection of databases published on disk and CD-ROM and updated quarterly, containing the Cochrane Database of Systematic Reviews, the Cochrane Controlled Trials Register, the Database of Abstracts of Reviews of Effectiveness, the Cochrane Review Methodology Database, and information about the Cochrane Collaboration.

## **Cohort study (synonyms: follow-up, incidence, longitudinal, prospective study)**

An observational study in which a defined group of people (the cohort) is followed over time and outcomes are compared in subsets of the cohort who were exposed or not exposed, or exposed at different levels, to an intervention or other factor of interest. Cohorts can be assembled in the present and followed into the future (a “concurrent cohort study”), or identified from past records and followed forward from that time up to the present (a “historical cohort study”). Because random allocation is not used, matching or statistical adjustment must be used to ensure that the comparison groups are as similar as possible.

## **Concealment of allocation**

The process used to prevent foreknowledge of group assignment in a randomised-controlled trial, which should be seen as distinct from blinding. The allocation process should be impervious to any influence by the individual making the allocation by having the randomisation process administered by someone who is not responsible for recruiting participants; for example, a hospital pharmacy, or a central office. Using methods of assignment such as date of birth and case record numbers (see quasi-random allocation) are open to manipulation. Adequate methods of allocation concealment include: centralized

randomisation schemes; randomisation schemes controlled by a pharmacy; numbered or coded containers in which capsules from identical-looking, numbered bottles are administered sequentially; on-site computer systems, where allocations are in a locked unreadable file; and sequentially numbered opaque, sealed envelopes.

### **Confidence interval (CI)**

The range within which the “true” values (e.g. size of effect of an intervention) are expected to lie with a given degree of certainty (e.g. 95% or 99%). Note: Confidence intervals represent the probability of random errors, but not systematic errors (bias).

### **Confounding**

A situation in which a measure of the effect of an intervention or exposure is distorted because of the association of exposure with other factor(s) that influence the outcome under study.

### **Consumer (health care consumer)**

Someone, who uses, is affected by, or who is entitled or compelled to use a health-related service.

### **Control**

1. In clinical trials comparing two or more interventions, a control is a person in the comparison group that receives a placebo, no intervention, usual care or another form of care.
2. In case-control studies a control is a person in the comparison group without the disease or outcome of interest.
3. In statistics control means to adjust for or take into account extraneous influences or observations.
4. Control can also mean programmes aimed at reducing or eliminating the disease when applied to communicable (infectious) diseases.

### **Controlled clinical trial (CCT)**

Refers to a study that compares one or more intervention groups to one or more comparison (control) groups. Whilst not all controlled studies are randomised, all randomised trials are controlled.

### **Critical appraisal**

The process of assessing and interpreting evidence by systematically considering its validity, results and relevance.

### **Cross-sectional study (synonym: prevalence study)**

A study that examines the relationship between diseases (or other health-related characteristics) and other variables of interest as they exist in a defined population at one particular time. The temporal sequence of cause and effect cannot necessarily be determined in a cross-sectional study.

### **Cross-over trial**

A type of clinical trial comparing two or more interventions in which the participants, upon completion of the course of one treatment are switched to another. For example, for a comparison of treatments A and B, half the participants are randomly allocated to receive

them in the order A, B and half to receive them in the order B, A. A problem with this design is that the effects of the first treatment may carry over into the period when the second is given.

## **Database**

A collection of organised information usually held on a computer. In some ways a database is similar to a filing system, but with important advantages: the information can be revised and kept up to date easily, and the computer can retrieve information from it very quickly. Electronic databases such as MEDLINE, EMBASE and the CDSR can be distributed on disk, CD-ROM or via the Internet.

## **Database of Abstracts of Reviews of Effectiveness (DARE)**

A collection of structured abstracts and bibliographic references of systematic reviews of the effects of healthcare. See the Cochrane Library.

## **Detection bias (synonym: ascertainment bias)**

Systematic differences between comparison groups in how outcomes are ascertained, diagnosed or verified.

## **Dichotomous data (synonym: binary data)**

Observations with two possible categories such as dead/alive, smoker/non-smoker, present/not present.

## **Double blind (synonym: double masked)**

Neither the participants in a trial nor the investigators (outcome assessors) are aware of which intervention participants are given. The purpose of blinding the participants (recipients and providers of care) is to prevent performance bias. The purpose of blinding the investigators (outcome assessors, who might also be the care providers) is to protect against detection bias. See also blinding, single blind, triple blind, and concealment of allocation.

## **Effect size**

1. A generic term for the estimate of effect for a study.
2. A dimensionless measure of effect that is typically used for continuous data when different scales (e.g. for measuring pain) are used to measure an outcome and is usually defined as the difference in means between the intervention and control groups divided by the standard deviation of the control or both groups. See standardised mean difference.

## **Effectiveness**

The extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do. Clinical trials that assess effectiveness are sometimes called management trials. See also intention-to-treat.

## **Efficacy**

The extent to which an intervention produces a beneficial result under ideal conditions. Clinical trials that assess efficacy are sometimes called explanatory trials and are restricted to participants who fully co-operate.

## **Epidemiology**

The study of the distribution and determinants of health-related states or events in specified populations.

### **Estimate of effect (synonym: treatment effect)**

In studies of the effects of health care, the observed relationship between an intervention and an outcome expressed as, for example, a number needed to treat, odds ratio, risk difference, relative risk, standardised mean difference, or weighted mean difference.

### **Event rate**

The proportion of participants in a group in whom an event is observed. Thus, if out of 100 patients the event (e.g. a stroke) is observed in 32, the event rate is 0.32.

### **Evidence-based health care**

The conscientious use of current best evidence in making decisions about the care of individual patients or the delivery of health services.

### **External peer reviewer**

A person with relevant content, methodological or user expertise who critically examines reviews in her/his area of expertise.

### **External validity (synonyms: external validity, generalisability, relevance, transferability)**

The degree to which the results of an observation hold true in other settings. See also validity.

### **Fixed effect model**

A statistical model that stipulates that the units under analysis (e.g. people in a trial or study in a meta-analysis) are the ones of interest, and thus constitute the entire population of units. Only within-study variation is taken to influence the uncertainty of results (as reflected in the confidence interval) of a meta-analysis using a fixed effect model. Variation between the estimates of effect from each study (heterogeneity) does not affect the confidence interval in a fixed effect model. See random effects model.

### **Generalisability (synonyms: applicability, external validity, relevance, and transferability)**

Generalisability is the degree to which the results of a study or systematic review can be extrapolated to other circumstances, in particular to routine health care situations.

### **Gold standard**

The method, procedure or measurement that is widely accepted as being the best available against which new interventions should be compared. It is particularly important in studies of the accuracy of diagnostic tests. For example, hand searching is sometimes used as the gold standard for identifying trials against which electronic searches of databases, such as MEDLINE are compared.

### **Heterogeneity**

In systematic reviews heterogeneity refers to variability or differences between studies in the estimates of effects. A distinction is sometimes made between “statistical heterogeneity” (differences in the reported effects), “methodological heterogeneity” (differences in study design) and “clinical heterogeneity” (differences between studies in key characteristics of the

participants, interventions or outcome measures). Statistical tests of heterogeneity are used to assess whether the observed variability in study results (effect sizes) is greater than that expected to occur by chance. However, these tests have low statistical power. See also homogeneity.

### **Incidence**

The number of new cases of a disease, or event, in a population during a specific period of time.

### **Individual patient data**

In systematic reviews this term refers to the availability of raw data for each study participant in each included trial, as opposed to aggregate data (summary data for the comparison groups in each study). Reviews using individual patient data require collaboration of the investigators who conducted the original trials, who must provide the necessary data.

### **Intention-to-treat**

An intention-to-treat analysis is one in which all the participants in a trial are analysed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favored in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice and because of the risk of attrition bias when participants are excluded from the analysis.

### **Mean (synonyms: arithmetic mean, average)**

The average value calculated by adding all the observations and dividing by the number of observations.

### **MEDLINE (MEDlars onLINE)**

An electronic database produced by the United States National Library of Medicine. It indexes millions of articles in selected (about 3700) journals. It is available through most medical libraries, and can be accessed on CD-ROM, the Internet and by other means. Years of coverage: 1966 to the present.

### **MeSH headings (Medical Subject Headings)**

Terms used by the United States National Library of Medicine to index articles in Index Medicus and MEDLINE. Designed to reduce problems that arise from, for example, differences in British and American spelling. The MeSH system has a tree structure in which broad subject terms branch into a series of progressively narrower subject terms.

### **Meta-analysis**

The use of statistical techniques in a systematic review to integrate the results of the included studies. Also used to refer to systematic reviews that use meta-analysis.

### **Meta-regression**

Multivariate meta-analytic techniques, such as logistic regression, used to explore the relationship between study characteristics (e.g. allocation concealment, baseline risk, timing of the intervention) and study results (the magnitude of effect observed in each study) in a systematic review.

### **Methodological quality (synonyms: validity, internal validity)**

The extent to which the design and conduct of a trial are likely to have prevented systematic errors (bias). Variation in quality can explain variation in the results of trials included in a systematic review. More rigorously designed (better “quality”) trials are more likely to yield results that are closer to the “truth”. See also external validity, validity.

### **Negative study**

A term used to refer to a study that does not have “statistically significant” (positive) results indicating a beneficial effect of the intervention being studied. The term can generate confusion because it refers to both statistical significance and the direction of effect, studies often have multiple outcomes, the criteria for classifying studies as “negative” are not always clear and, in the case of studies of risk or undesirable effects, “negative” studies are ones that do not show a harmful effect. See also positive study.

### **Null hypothesis**

The statistical hypothesis that one variable (e.g. whether or not a study participant was allocated to receive an intervention) has no association with another variable or set of variables (e.g. whether or not a study participant died), or that two or more population distributions do not differ from one another. In simplest terms, the null hypothesis states that the results observed in a study are no different from what might have occurred as a result of the play of chance.

### **Number needed to treat (NNT)**

The number of patients who need to be treated to prevent one bad outcome. It is the inverse of the risk difference.

### **Observational study (synonym: non-experimental study)**

A study in which nature is allowed to take its course. Changes or differences in one characteristic (e.g. whether or not people received the intervention of interest) are studied in relation to changes or differences in other(s) (e.g. whether or not they died), without the intervention of the investigator. There is a greater risk of selection bias than in experimental studies (randomised controlled trials).

### **Odds ratio (OR)**

The ratio of the odds of an event in the experimental (intervention) group to the odds of an event in the control group. Odds are the ratio of the number of people in a group with an event to the number without an event. Thus, if a group of 100 people had an event rate of 0.20, 20 people had the event and 80 did not, and the odds would be 20/80 or 0.25. An odds ratio of one indicates no difference between comparison groups. For undesirable outcomes an OR that is less than one indicates that the intervention was effective in reducing the risk of that outcome. When the event rate is small, odds ratios are very similar to relative risks.

### **Peer review**

A refereeing process used to check the quality and importance of reports of research. An article submitted for publication in a peer reviewed journal is reviewed by other experts in the area. It aims to provide a wider check on the quality and interpretation of a report and to improve its quality. See also external peer reviewer.

### **Performance bias**

Systematic differences in care provided apart from the intervention being evaluated. For example, if patients know they are in the control group they may be more likely to use other forms of care, patients who know they are in the experimental (intervention) group may

experience placebo effects, and care providers may treat patients differently according to what group they are in. Blinding of study participants (both the recipients and providers of care) is used to protect against performance bias.

### **Placebo**

An inactive substance or procedure administered to a patient, usually to compare its effects with those of a real drug or other intervention, but sometimes for the psychological benefit to the patient through a belief that s/he is receiving treatment. Placebos are used in clinical trials to blind people to their treatment allocation. Placebos should be indistinguishable from the active intervention to ensure adequate blinding.

### **Placebo effect**

A favourable response to an intervention, regardless of whether it is the real thing or a placebo, attributable to the expectation of an effect, i.e. the power of suggestion. The effects of many health care interventions are attributable to a combination of both placebo and “active” (non-placebo) effects.

### **Positive study**

A term used to refer to a study with results indicating a beneficial effect of the intervention being studied. The term can generate confusion because it can refer to both statistical significance and the direction of effect, studies often have multiple outcomes, and the criteria for classifying studies as negative or positive are not always clear and, in the case of studies of risk or undesirable effects, “positive” studies are ones that show a harmful effect. See also negative study.

### **Precision**

1. A measure of the likelihood of random errors in the results of a study, meta-analysis or measurement. Confidence intervals around the estimate of effect from each study are a measure of precision, and the weight given to the results of each study in a meta-analysis (typically the inverse of the variance of the estimate of effect) is a measure of precision (i.e. the degree to which a study influences the overall estimate of effect in a meta-analysis is determined by the precision of its estimate of effect).
2. The proportion of relevant citations located using a specific search strategy, i.e. the number of relevant studies (meeting the inclusion criteria for a trials register or a review) divided by the total number of citations retrieved.

### **Prevalence**

The number of existing cases of a particular disease or condition in a given population at a designated time.

### **Probability**

The function that gives the probabilities that a variable equals each of a sequence of possible values. Examples include the binomial, chi square, normal and Poisson distributions.

### **Prospective study**

In evaluations of the effects of health care interventions, a study in which people are divided into groups that are exposed or not exposed to the intervention(s) of interest before the outcomes have occurred. Randomised controlled trials are always prospective studies and case control studies never are. Concurrent cohort studies are prospective studies, whereas historical cohort studies are not (see cohort study), although in epidemiology a prospective study is sometimes used as a synonym for cohort study. See also retrospective study.



### **Publication bias**

A bias in the published literature where the publication of research depends on the nature and direction of the study results. Studies in which an intervention is not found to be effective are sometimes not published. Because of this, systematic reviews that fail to include unpublished studies may overestimate the true effect of an intervention.

### **P-value**

The probability (ranging from zero to one) that the observed results in a study, or results more extreme, could have occurred by chance. In a meta-analysis the *P*-value for the overall effect assesses the overall statistical significance of the difference between the treatment and control groups, whilst the *P*-value for the heterogeneity statistic assesses the statistical significance of differences between the effects observed in each study.

### **Quasi-random allocation**

A method of allocating participants to different forms of care that is not truly random; for example, allocation by date of birth, day of the week, medical record number, month of the year, or the order in which participants are included in the study (e.g. alternation).

### **Quasi-randomised trial**

A trial using a quasi-random method of allocating participants to different forms of care. There is a greater risk of selection bias in quasi-random trials where allocation is not adequately concealed compared with randomised controlled trials with adequate concealment of allocation.

### **Random allocation**

A method that uses the play of chance to assign participants to comparison groups in a trial, e.g. by using a random numbers table or a computer-generated random sequence. Random allocation implies that each individual or unit being entered into a trial has the same chance of receiving each of the possible interventions. It also implies that the probability that an individual will receive a particular intervention is independent of the probability that any other individual will receive the same intervention. See also concealment of allocation, quasi-random allocation, randomisation.

### **Random effects model**

A statistical model sometimes used in meta-analysis in which both within-study sampling error (variance) and between-studies variation are included in the assessment of the uncertainty (confidence interval) of the results of a meta-analysis. See fixed effect model. If there is significant heterogeneity among the results of the included studies, random effects models will give wider confidence intervals than fixed effect models.

### **Random selection (synonym: random sampling)**

A method of obtaining a representative, unbiased group of people from a larger population. Random selection which is not related to how participants are allocated to comparison groups is frequently used in cross-sectional and cohort studies, which are not randomised controlled trials, and it is frequently not used in randomised controlled trials. In older trial reports, however, the term is occasionally used instead of random allocation or randomisation.

### **Randomisation (spelled randomization in US English)**

Method used to generate a random allocation sequence, such as using tables of random numbers or computer-generated random sequences. The method of randomisation should be distinguished from concealment of allocation because of the risk of selection bias despite

the use of randomisation, if there is not adequate allocation concealment. For instance, a list of random numbers may be used to randomise participants, but if the list is open to the individuals responsible for recruiting and allocating participants, those individuals can influence the allocation process, either knowingly or unknowingly.

**Randomised controlled trial (RCT) (Synonym: randomised clinical trial)**

An experiment in which investigators randomly allocate eligible people into (e.g. treatment and control) groups to receive or not to receive one or more interventions that are being compared. The results are assessed by comparing outcomes in the treatment and control groups. NOTE: when using randomised controlled trial as a search term (publication type) in MEDLINE, the US spelling (randomised) must be used.

**Relative risk (RR) (synonym: risk ratio)**

The ratio of risk in the intervention group to the risk in the control group. The risk (proportion, probability or rate) is the ratio of people with an event in a group to the total in the group. A relative risk of one indicates no difference between comparison groups. A relative risk of one indicates no difference between comparison groups. For undesirable outcomes a RR that is less than one indicates that the intervention was effective in reducing the risk of that outcome.

**Reliability**

Refers to the degree to which results obtained by a measurement procedure can be replicated. Lack of reliability can arise from divergences between observers or measurement instruments, or instability in the attribute being measured.

**Retrospective study**

A study in which the outcomes have occurred to the participants before the study commenced. Case control studies are always retrospective, cohort studies sometimes are, randomised controlled trials never are. See prospective study.

**Review**

1. A systematic review.
2. A review article in the medical literature, which summarises a number of different studies and may draw conclusions about a particular intervention. Review articles are often not systematic. Review articles are also sometimes called overviews.
3. To referee a paper. See referee, referee process, external peer reviewer.

**Risk difference (RD) (synonym: absolute risk reduction)**

The absolute difference in the event rate between two comparison groups. A risk difference of zero indicates no difference between comparison groups. For undesirable outcomes a RD that is less than zero indicates that the intervention was effective in reducing the risk of that outcome.

**Risk factor**

Aspects of a person's condition, lifestyle or environment that increase the probability of occurrence of a disease. For example, cigarette smoking is a risk factor for lung cancer.

### **Selection bias**

1. In assessments of the validity of studies of health care interventions, selection bias refers to systematic differences between comparison groups in prognosis or responsiveness to treatment. Random allocation with adequate concealment of allocation protects against selection bias. Other means of selecting who receives the intervention of interest, particularly leaving it up to the providers and recipients of care, are more prone to bias because decisions about care can be related to prognosis and responsiveness to treatment.
2. Selection bias is sometimes used to describe a systematic error in reviews due to how studies are selected for inclusion. Publication bias is an example of this type of selection bias.
3. Selection bias, confusingly, is also sometimes used to describe a systematic difference in characteristics between those who are selected for study and those who are not. This affects the generalisability (external validity) of a study but not its (internal) validity.

### **Sensitivity analysis**

An analysis used to determine how sensitive the results of a study or systematic review are to changes in how it was done. Sensitivity analyses are used to assess how robust the results are to uncertain decisions or assumptions about the data and the methods that were used.

### **Single blind (synonym: single masked)**

The investigator is aware of the treatment/intervention the participant is getting, but the participant is unaware. See also blinding, double blind, triple blind.

### **Standardised mean difference**

The difference between two means divided by an estimate of the within-group standard deviation. When an outcome (such as pain) is measured in a variety of ways across studies (using different scales) it may not be possible directly to compare or combine study results in a systematic review. By expressing the effects as a standardised value the results can be combined since they have no units. Standardised mean differences are sometimes referred to as a d index.

### **Statistical power**

The probability that the null hypothesis will be rejected if it is indeed false. In studies of the effectiveness of health care interventions, power is a measure of the certainty of avoiding a false negative conclusion that an intervention is not effective when in truth it is effective. The power of a study is determined by how large it is (the number of participants), the number of events (e.g. strokes) or the degree of variation in a continuous outcome (such as weight), how small an effect one believes is important (i.e. the smallest difference in outcomes between the intervention and the control groups that is considered to be important), and how certain one wants to be of avoiding a false positive conclusion (i.e. the cut-off that is used for statistical significance).

### **Statistical significance**

An estimate of the probability of an association (effect) as large as or larger than what is observed in a study occurring by chance, usually expressed as a *P*-value. For example, a *P*-value of 0.049 for a risk difference of 10% means that there is less than a one in 20 (0.05) chance of an association that is as large or larger having occurred by chance and it could be said that the results are “statistically significant” at  $P = 0.05$ ). The cut-off for statistical significance is usually taken at 0.05, but sometimes at 0.01 or 0.10. These cut-offs are arbitrary and have no specific importance. Although it is often done, it is inappropriate to

interpret the results of a study differently according to whether the *P*-value is, say, 0.055 or 0.045 (which are quite similar values, not diametrically opposed ones).

**Systematic review (synonym: systematic overview)**

A review of a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies.

**Trials register**

In the Cochrane Collaboration, this is a database of bibliographic references to randomised controlled trials and controlled clinical trials relevant to a Collaborative Review Group or Field that is maintained at the editorial base. Software such as ProCite or Reference Manager is used to manage the database. Once a relevant report of a trial is identified, it is photocopied, coded and entered onto the register. Wherever possible, relevant trial reports are downloaded directly into the register from an electronic database such as MEDLINE. Information about unpublished and ongoing trials is also included in trials registers.

**Triple blind (synonym: triple masked)**

An expression that is sometimes used to indicate that knowledge of which study participants are in which comparison group is kept secret from the statistician doing the analysis as well as from the study participants and investigators (outcome assessors). See also blinding, single blind, double blind.

**Validity (synonym: internal validity)**

Validity is the degree to which a result (of a measurement or study) is likely to be true and free of bias (systematic errors). Validity has several other meanings, usually accompanied by a qualifying word or phrase; for example, in the context of measurement, expressions such as “construct validity”, “content validity” and “criterion validity” are used. The expression “internal validity” is sometimes used to distinguish validity (the extent to which the observed effects are true for the people in a study) from external validity or generalisability (the extent to which the effects observed in a study truly reflect what can be expected in a target population beyond the people included in the study).

**Variable**

Any quantity that varies. A factor that can have different values.



## **Presentations**

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**Module 2**

**Module 3**

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**Module 13**



# **Making evidence-based decisions in reproductive health: a training course**

FACILITATOR MANUAL

WHO PROGRAMME TO MAP BEST REPRODUCTIVE HEALTH PRACTICES