Module 4: **Evidence**

Structure of the Evidence Module

SESSION 1 Collection and interpretation of data

Provides a refresher on the use of health statistics. Illustrates challenges in generating good information on sensitive sexual and reproductive health topics. Discusses the concept "generalizability" of data and sources of bias.

SESSION 2 The research process step by step

Provides an overview of basic concepts in health research: research question(s), sample population and study design. Introduces the concept of a gender perspective in health research.

SESSION 3 Ethical issues in reproductive health research

Provides insights into key ethical dilemmas in reproductive health research, from a gender perspective. Acquaints participants with principles of ethics in research, focusing on reproductive health. Presents international ethical guidelines for the conduct of research.

SESSION 4 Evidence for planning: reconciling evidence from different sources (Case: maternal health)

Provides skills at reconciling data from different sources for health planning. Provides experience in identifying gender bias in collecting, analysing, interpreting and presenting information.

SESSION 5 Evidence for policy and programming: selecting appropriate technologies for fertility regulation

Develops skills for identifying information needed to select technologies for fertility regulation appropriate to a given setting, integrating gender and rights concerns.

SESSION 6 Evidence for monitoring: reproductive health indicators

Builds skills for identifying most relevant reproductive health indicators in a given setting. Provides examples of indicators which incorporate gender and rights concerns.

SESSION 7 Evidence for service evaluation: applied exercises

Acquaints participants with a range of techniques for data/information collection for service evaluation. Provides hands-on skills in constructing tools for data/information collection, and helps participants learn how to integrate gender and rights dimensions in data/information collection for monitoring, surveillance and evaluation of services.

MODULE 4

Module brief

What participants should get out of the Evidence Module

Participants will:

- be familiar with basic concepts in health research and be able to identify types of evidence that are useful to reproductive health service planning and policy
- be familiar with common examples of research bias, including gender bias, in the collection, interpretation and presentation of health information
- be aware of current international guidelines for ethical practice in health research and how they apply to current controversies in reproductive health research
- be able to identify relevant reproductive health indicators in a given setting that incorporate gender and rights.
- have acquired skills in health systems appraisal, technology assessment and service evaluation that incorporate a gender and rights perspective.

The thinking behind the module

What research can be used for

Health research, and the evidence it generates, makes it possible to identify:

- health problems
- the determinants of those problems
- the interventions needed
- the impact of interventions.

Among health systems planners, useful evidence will identify health seeking and service utilization rates, and the improvements that health delivery systems need. Monitoring and evaluation allow short term or ongoing reassessments of whether specific interventions, technologies or services are having the desired impact. Long term monitoring and surveillance systems allow the health system to be adapted to changing health needs.

How research can fail women

Evidence which we use to evaluate whether a health system is effective or whether given technologies or interventions are optimal, should include attention to the needs and concerns of potential clients. Unfortunately, the evidence on which reproductive health services and family planning technologies have been evaluated has often paid scant attention to the rights or the broader health and social needs of clients, who are mostly women. The evidence has frequently failed to include information on whether rights relevant to women's reproductive health are protected, whether the available services match prevailing health needs, or even whether the minimum standards of good practice are being met. This neglect reflects both the long-standing low status of women and the specific interest of states in controlling women's fertility rather than promoting their well-being.

Evidence needs to be reoriented

Strengthening reproductive health systems to promote gender equality and reproductive rights requires, therefore, a reorientation of the types of evidence used for assessing needs, measuring the quality of services, evaluating interventions, and monitoring impact over the longer term. This is the purpose of this module.

Session 1 provides participants with a refresher on health statistics and basic research terminology, while highlighting the challenge of collecting data on sensitive topics in sexual and reproductive health research. By using participants' own data on the timing of their first sexual and reproductive experience, the session provides a review of sampling, bias, and generalizability. Courses directed at more senior researchers may choose to skip the emphasis on research fundamentals in Session 1 and focus on the discussion on gender differentials in sexual norms, conjugal age differences, and recent trends in the timing of sexual and reproductive events.

Session 2 provides a step by step review of the research process, describing a range of study designs and their applications. Participants are presented with short research problems and given the chance to walk through the steps, from framing the research question(s), to defining the sample population and sample selection, to identifying a suitable mix of methods for pursuing the research question(s). The examples range from simple to complex problems. This session refers back to the gender and health session of the Gender Module (Module 1, Session 5) and concepts learnt in the Rights Module (Module 3) to illustrate the effect of applying a gender and rights perspective to all steps in the research process.

Session 3 provides participants with international guidelines for ethical health research, because gathering information may conflict with patient privacy or the immediate provision of care. Ethical research dilemmas within reproductive health are accentuated by gender inequalities – women are often the objects of reproductive health research in settings where they lack the social status to ensure the protection of their health and rights. The legacy of population control in many settings further compromises women's choices (and sometimes men's) in relation to participation in family planning research when overzealous concern for population control is allowed to override ethical concerns in contraceptive trials or accepted standards in clinical care. The session is designed as a formal debate to provide participants with a chance to enhance their skills in articulating and advocating for ethical principles.

Session 4 provides participants with an opportunity to apply a gender analysis to research reports and articles, and to identify sources of gender bias in the way data is collected, analysed, interpreted or presented. The session then looks at how potential planning mistakes may emerge if decisions are based on only one type of evidence. It builds on the preceding session by providing concrete examples of how different research methods highlight different aspects of a given problem, and how recommendations for action reflect the type of evidence that has been used. The exercise emphasizes the value of reconciling data from different sources to identify plans that will be effective and long lasting. The case material provided is on maternal health, but other examples can be used as the method is generalizable to other health problems.

Session 5 offers a concrete example of how to identify information needs that will accommodate gender and rights concerns in the selection of fertility regulation technologies. There is strong emphasis on the need to:

- address both fertility regulation and disease prevention in a given setting
- promote and protect reproductive rights
- promote shared responsibility among men and women while ensuring attention to women's urgent practical needs.

The overall framework for selecting effective fertility regulation technologies can be applied to other technologies (for example, technologies for diagnosing sexually transmitted infections (STIs)). But the example provided shows how existing family planning programmes can be systematically re-evaluated in a way that is consistent with the Cairo and Beijing agendas.

Session 6 introduces the concept of indicators and how they can be used in monitoring health status, the utilization of services and service quality. There is an emphasis on demystifying indicators as something only necessary for external monitors, and on their usefulness as a self-generated tool for the ongoing monitoring of quality control, performance and impact. Participants will acquire skills to identify the reproductive health indicators that will be most useful in a given setting, and you will show them a range of existing and new indicators that can be used to monitor gender equity and reproductive rights in sexual and reproductive health.

Session 7 provides hands-on exercises in the development of tools for the evaluation of services. These group exercises give participants first hand exposure to the difficulties in constructing tools for gathering information, and thus increase their understanding of what concepts like bias, validity or generalizability mean in practice. The discussion questions for each exercise highlight how gender and rights dimensions can be addressed in data/information collection.

Module outline

		Objectives Participants will:	Format of activities	Time: about 18 hours
Introductory session	Introduction to the Evidence Module	• be acquainted with module objectives and contents	Input session	15 mins
SESSION 1	Collection and interpretation of data	• be re-acquainted with the use and value of simple statistical measures: mean, median, range and variance • be introduced to the notion of confidentiality, sensitivity in sexual and reproductive data, and ways of protecting the privacy of research subjects • discuss the interpretation and generalizability of data, and concepts of bias	Data collection exercise conducted prior to the session Input Facilitated discussion	1 hr 40 mins (outside class time) 1 hr 15 mins 30 mins
SESSION 2	The research process step by step	• be acquainted with basic steps in the designing of a research study • be introduced to the concept of a gender and rights perspective in health research	Input Participatory exercises in whole group	50 mins 40 mins
SESSION 3	Ethical issues in reproductive health research	• be acquainted with principles of ethics in research, focusing on reproductive health • have an overview of international ethical guidelines for the conduct of research • debate key ethical dilemmas in reproductive health research from a gender perspective	Introductory lecture Group work to prepare for debate Debate and discussion	1 hr 30 mins 1 hr
SESSION 4	Evidence for planning: reconciling evidence from different sources (Case: maternal health)	• recognize that research results reflect what question was asked, how the evidence was gathered, and from whom it was solicited • understand the need to reconcile evidence from different sources for sound decision making • be able to identify gender bias in the collection, analysis, interpretation and presentation of health information	Individual reading Small group work Report-backs and whole group discussion	outside class hours 40 mins 1 hr 40 mins
SESSION 5	Evidence for policy and programming: selecting appropriate technologies for fertility regulation	• develop skills for identifying information needs for selecting fertility regulation technologies appropriate to a given setting • be able to integrate gender and rights concerns when making this selection	Input by facilitator Small group work Report-backs and discussion in whole group	45 mins 1 hr 1 hr
SESSION 6	Evidence for monitoring and evaluation: reproductive health indicators	• be familiar with different types of health indicators and their uses • come up with indicators most relevant to specific settings • have the skills to use and/or develop indicators that capture the gender and rights dimensions of a health issue or problem	Input by facilitator Quiz Small group exercise(s) followed by plenary	30 mins 15 mins 1 hr 30 mins
SESSION 7	Evidence for service evaluation: applied exercises	• be acquainted with a range of techniques for data/information collection for service evaluation • have hands-on practice in constructing tools for data/information collection • learn how to integrate gender and rights dimensions in the monitoring and/or evaluation of services	Input by facilitator Hands-on group exercise Group presentations and whole group discussion	30 mins 3 hrs 2 hrs

Introduction to the Evidence Module

What participants should get out of the Evidence Module

Participants will:

Participants will be familiar with the structure, contents and objectives of Module 4.

15 minutes

How to run the session

This is an input session.

Introduce the module using **overheads** from the Module brief:

- "What participants should get out of the Evidence Module"
- "Structure of the Evidence Module"
- "Module outline".

SESSION 1

Collection and interpretation of data

What participants should get out of the session

Participants will:

- be re-acquainted with the use and value of simple statistical measures: mean, median, range and variance
- discuss the interpretation and generalizability of data, and concepts of bias
- be introduced to the notion of confidentiality and sensitivity in sexual and reproductive health data, and ways of protecting the privacy of research subjects.

1 hr 40 mins

1 hour and 40 minutes

Prior preparation

- The data gathering exercise has to be done the previous day. See description under Activity 1 below.

Materials

- 3 large pieces of newsprint for data sheets, as on p.214
- overhead: Summary statistics from data generated by participants on their first sexual and reproductive experience, example on p.215
- overhead: “Variables”, on p.216
- overhead: “An overview of summary statistics”, on p.217

How to run the session

This session combines three complementary activities. The first is to collect and analyse data on the timing of sexual and reproductive events. Note that participants must complete this first activity in their own time on the day before you start this session. The second activity is a whole group discussion, based on the data generated, which explores gender differentials in sexual norms, and gender role expectations in relation to age, power and responsibility for reproduction. The third activity is a discussion about gendered sexual norms and reproductive experiences, based on the data that participants have generated.

Activity 1: Gathering data

Allow 10–15 minutes on the day before the session to introduce this activity. When participants have completed the data sheets, you analyse the data in your own time and prepare an input for the next day.

Step 1: The data collection sheet

Prepare two or three large pieces of newsprint with the following table, with enough lines to allow one per participant, plus an extra five lines.

Data sheet – First sexual and reproductive experience

M or F	Age at first menses (F) or when voice changed (M)		Age at first sex		Age at first pregnancy (F) or age at first pregnancy of partner (M)		Age at first birth		Age at first marriage	
	You	Your partner (indicate M or F)	You	Your partner (indicate M or F)	You	Your partner (indicate M or F)	You	Your partner (indicate M or F)	You	Your partner (indicate M or F)
1										
2										
3										
4										
etc.										

Step 2: Put the data collection sheet somewhere private

Put the data sheet somewhere that will ensure privacy for those filling it in. You and another course facilitator should fill in your own data on any vacant lines, so that two data lines are already completed. But not lines 1 and 2 – in this way, no one will know which data corresponds to which participant.

Step 3: Explain how to fill it in

Participants can fill in the data sheet in any of their breaks. Ask each member of the group to go alone to the data sheet and fill in their personal information. Explain that they can use any free line, not necessarily the very next open one. Also explain that:

- "Your partner" refers to the partner with whom you first had sex, or the partner you first married, not your current partner.
- If a question does not apply to you, for example if you have never been married, put a dash.
- If you don't have the information, for example, you do not know the age of the person who was the "father" of your first pregnancy, then put a question mark. This differentiates questions that do not apply from missing data, a point you may want to explore later.

Step 4: Analyse the data

Once the data sheet has been completed, do an analysis of the data in your own time. Calculate the following summary statistics from the data:

- range
- mean
- median
- mode
- standard deviation.

Prepare an overhead of the results of your analysis. The box below "Example of summary statistics from data generated by participants on their first sexual and reproductive experience" gives an example from one of the courses.

Example of summary statistics from data generated by participants on their first sexual and reproductive experience

Sample size = 37; Females = 34; Males = 3

1. Age at first menses
Range: 11–17
Mean: 13.4
Median: 13
Mode: 13
Standard deviation: 1.8

2. Age at first sex
Range: 9–28
Mean: 19.1
Median: 19
Mode: 18
Standard deviation: 3.8

58% of the women had their first sexual experience under age 20

3. Age of first sexual partner
Range: 14–45
Mean: 22.3
Median: 21
Mode: 19
Standard deviation: 5.5

66% of first sexual partners were over age 20

4. Age at first pregnancy
Range: 16–36
Mean: 24.1
Median: 23.5
Mode: 21
Standard deviation: 5.3

20% of the women in the sample had their first pregnancy under age 20

5. Age at first marriage
Range: 20–30
Mean: 25.3
Median 25
Mode: 25
Standard deviation: 2.9

6. Age of partner at first marriage
Range: 22–36
Mean: 27.8
Median: 27
Mode: 23
Standard deviation: 4.2

1 hr 15 mins

Activity 2: Discussing the data

10 mins

Step 1: Whole group discussion: sensitive issues

Start the session by asking participants how they felt putting personal information down on the data collection sheet. Find out if they thought that the process had respected confidentiality. Take about 10 minutes for this discussion. Mention that this is a key element in the *International ethical guidelines for biomedical research involving human subjects*, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization in 1993. (See Session 3 in this module.)

Ask whether there are other sexual and reproductive health data that are highly sensitive, and discuss the limitations of conducting research on such topics. Probe to find out if participants can think of other important reasons for ensuring confidentiality when collecting sensitive data, other than for ethical reasons. Some examples would be social stigma, or concern for the safety of the respondent (in the case of women experiencing domestic violence, for instance). Go through one or two examples, such as induced abortion, substance abuse, or HIV/AIDS.

What to cover in the discussion

Take the utmost care with this sensitive data

Information/data related to reproductive and sexual health is highly sensitive. We need to take the utmost care in maintaining confidentiality, in both the data gathering as well as the reporting processes.

Reporting bias compromises the data

When respondents are not comfortable with answering certain questions, they may not respond at all or respond inaccurately. In the case of early sexual experience or abortion, for example, there may be a common tendency to under-report. This is called systematic under-reporting or reporting bias, and compromises the quality of the data.

15 mins

Step 2: Variables

Put up an **overhead** containing the list of variables.

Variables

Age at first menses (females)
Age at which voice changed (males)
Age at first sex (females/males)
Age of first sexual partner (females/males)
Age at first pregnancy (females)
Age of partner at first pregnancy (females/males)
Age at first marriage (wives/husbands)
Age at first birth (mothers/fathers)

Ask participants what analysis can be done using these variables. Some usual responses are: average age at first menses; average ages at first sex, pregnancy, marriage and birth; differences in these by sex; proportion of those sexually active in adolescence; percentage of teenage pregnancies.

20 mins

Step 3: Review the summary statistics

Put up your **overhead** containing summary statistics from the data generated by participants. Review the summary statistics.

When presenting the data, ask participants to define the different summary statistics: range, mean, median, mode and standard deviation. Explain each of these and the differences between them.

An overview of summary statistics

Range = the smallest and largest values.

Mean = the sum of the observed values/number of values. The mean is sensitive to extreme values. In other words, two observations as different as 1 and 9 would give a mean value of 5. (1+9)/2 =5.

Median = the middle number of a set of numbers arranged in numerical order. If there is an even number of values, the median is the result of adding the two middle values and dividing by 2. A median value of 13 for age at first menses means that 50 per cent of those in the sample had their first menses at age 13 or below. The median is not sensitive to extreme values, and hence is a better summary measure when the data are known to have outliers.

Mode = the value with the maximum number of observations. A mode value of 18 for age at first sex means that the number of respondents who had their first sexual experience at age 18 is greater than the number who had their first sexual experience at other ages in the range (9–28 years).

Standard deviation (SD) = an estimate of the variance, or the spread of the values about the mean. The standard deviation is a summary measure of the difference between each value and the mean. A high standard deviation means that the data values are widely dispersed around the mean, while a low standard deviation means that all values lie within a narrow range. For example, for the narrow range 11–17 years (of age at first menses), the SD is 1.8; for the broad range 14–45 years (of age of first sexual partner), the SD is 5.5.

30 mins

Step 4: Generalizability, sampling and sources of bias

Use this opportunity to discuss issues around the generalizability of data, sampling and sources of bias.

What to cover in the discussion

Generalizability

Ask the group if the data generated from this exercise would be true of their society in general, and, if not, in what way does the data differ? Define the concept of generalizability.

The sample

Ask participants to describe how they would define themselves as a sample of society as a whole. Get the group to list the demographic characteristics that would describe them.

Select a different age or social group (for example, a meeting of 65 years and older retirees). How might their data differ from that generated by the course participants? Make it explicit how these demographic characteristics are another way of talking about the social determinants of health or reproduction.

Sampling affects generalizability

The discussion moves on to the impact of sampling on the generalizability of data. Sampling is the process of selecting a number of study units from a defined study population. A representative sample has all the important characteristics of the population from which it is drawn. Therefore, information on a representative sample is generalizable to the population from which the sample is drawn.

It is not necessary to always choose samples to be representative. Purposive samples can also be used, depending on the research question. For example, to know the average age at menopause of women in a population we need a representative sample. But to understand women's perceptions of menopause we may actually want to include women with atypical responses in our sample in order to understand the entire range of perceptions.

Bias

What happens when there are errors in sampling procedures? This leads to a distortion in the results, or biases.

Some examples of sources of bias

- **The selection may not be random:** Willingness to take part in a study may attract persons who are anxious to get clinical care or treatment. For example, women willing to undergo a community screening study for reproductive morbidity may be those who perceive that they have a problem.

- **Certain members of the population may be omitted:** For example, surveys conducted during the day may exclude a majority of men and women working outside the home.

- **Non-response:** Substantial non-response is always worrisome. Those unwilling to answer questions may have no relevant experience, or they may have the greatest relevant experience, especially if the health problems being addressed are socially or morally sensitive (for example, domestic violence, abortion, or STIs).

- **Gender bias:** Females may be under-represented in the sample or vice-versa. For example, when STI incidence studies are based on clinic records there is a tendency to gender bias in the sample because users of STI services are predominantly males. For other health problems, the reverse may be true.

What are the sources of bias in the data generated from this group? The sample was self-selected, and we have agreed that the group cannot represent the population in this area.

How to review research fundamentals when some participants have previous exposure to research

Most courses on health systems draw participants with a wide range of prior research experience. You may find yourself trying to pitch a review of research fundamentals simultaneously to epidemiologists and to people with no training in research. How to handle this?

Prepare for the input on the previous day, forewarning the class that this is a refresher on fundamentals, and then hold to your commitment and pitch to the least experienced. Remember – in such a short session your goal is not to teach technical research skills, but concepts and judgement. And because conceptual training does well with multiple teachers, try to enlist the more experienced researchers to help you teach. Tell them ahead of time that you will be grateful for their assistance, and create time during the input for them to offer their own examples or to rephrase your definitions. In all likelihood the repetition and rephrasing will improve their understanding. And finally, remember that even busy researchers sometimes forget fundamentals and they may appreciate this more than you expect!

30 mins

Activity 3: Discussing gendered norms and experiences

Start a discussion on gendered sexual norms and reproductive experiences, based on the data that participants have generated and presented in the previous activity.

What to cover in the discussion

Young people

Why does the age at first sexual experience often differ for females and males? What is the common explanation for these differences? Explore gendered ideas about normal sexual behaviour among young males and females, including the social values of modesty and virginity. What are the positive and negative consequences of these different social expectations?

Age differences in couples

When first sex, marriage, or first births occur, how do the ages of the females and males within the couple differ? Is there any pattern? Why is this? How are typical age differences within couples linked to different expectations about power and responsibility? How do these coincide with differences in economic power? Or with life expectancy?

First sex, first marriage, first birth

In many parts of the world, recent trends show first sex occurring at earlier ages, while the age at marriage and first birth is getting later. What are the causes of these changes, and how do they coincide with changing social roles for males and females? What are the implications of these changes for reproductive health services?

Pregnancy before marriage

If the data suggest that some pregnancies occurred before marriage, explore the social expectations placed on each partner (mother, father) for pregnancies outside marriages. How do these impact on the reproductive health of males and females, and the need for services?

What is normal?

You can use this session to open discussions on current controversies about gender and sexual norms. For example:

- sexual roles and behaviours among adolescent girls and boys, and the positive and negative social effects of these differences
- recent trends in age at first sex, marriage and first birth, and the impact of these changes on girls and boys
- the social expectations placed on each partner (mother, father) when unplanned pregnancies occur
- typical age differences between husbands and wives, and the consequences.

Session developed by Rachel Snow and Sharon Fonn

SESSION 2

The research process step by step

What participants should get out of the session

Participants will:

- be acquainted with the step by step process of designing a research study
- be introduced to the concept of a gender perspective in health research.

1 hr 30 mins

1 hour and 30 minutes

Materials

- Handout 1: "Study designs"
- Handout 2: "Examples of problems addressed by health research"

- overhead: "Steps for research", on p.222
- overhead: "Overview of study designs", on p.225
- overhead: "Research questions, the study population and the study unit", on p.226
- overhead: "Some main points from the Gender Module, Session 5: Linking gender and health", on p.228
- overhead: Handout 2
- flip chart: "Questions for undertaking research", on p.229

How to run the session

This session consists of two activities: an interactive input by the facilitator, followed by an exercise in the whole group.

50 mins

Activity 1: Discussing research

5 mins

Step 1: What is research?

Start by asking participants what the word "research" means to them. Make the point that research is simply the act of finding out more about an issue or problem, with a specific purpose in mind.

Go over the objective of the session, that it aims at introducing the essential components of health research. Put up the **overhead** "Steps for research" from the box below.

Of the several steps outlined here, this session will look specifically at three: problem identification, specifying research objectives, and research methodology. Mention that participants will have an opportunity to design data collection tools in the last session of the module. Make it clear that this session does not attempt to teach them how to carry out research; it aims to acquaint participants with the research process in their capacity as health professionals who often use research information or who may commission research.

Steps for research

Problem identification

Literature review

Specifying the research question(s) and objective(s)

Research study design and methodology

Review of existing evidence/data

Data collection

Data processing

Data analysis

Report writing

Using research findings:
- Dissemination/feedback to respondents
- Application to policy and/or intervention

Source: Varkevisser CM et al. *Designing and conducting health systems research projects.* International Development Research Centre Canada. Health Systems Research Training Series, volume 2, part 1. Ottawa, IDRC, 1991.

5 mins

Step 2: Do you know where you're going?

As a way of starting the input on steps in health research, the following fable is used in the course in South Africa.

> From: Botha JL, Yach D. Manual of epidemiological research methods. A supplement of an abridged version of the IB-ESSA workshop manual, Tygerberg, South Africa Medical Research Council, 1987.
>
> Once upon a time a sea horse gathered up his seven pieces of eight and cantered to find his fortune. Before he had travelled very far, he met an eel, who said:
>
> "Psst. Hey bud. Where ya going?"
>
> "I'm going to find my fortune," replied the sea horse proudly.
>
> "You're in luck," said the eel. "For four pieces of eight you can have this speedy flipper, and then you'll be able to get there a lot faster."
>
> "Gee, that's swell," said the sea horse, and paid the money and put on the flipper, and slithered off at twice the speed.
>
> Soon he came upon a sponge, who said:
>
> "Psst. Hey bud. Where ya going?"
>
> "I'm going to find my fortune," replied the sea horse.
>
> "You're in luck" said the sponge. "For a small fee I will let you have this jet-propelled scooter so that you will be able to travel a lot faster."
>
> So the sea horse bought the scooter with his remaining money and went zooming through the sea five times as fast.
>
> Soon he came upon a shark, who said:
>
> "Psst. Hey bud. Where ya going?"
>
> "I'm going to find my fortune," replied the sea horse.
>
> "You're in luck. If you take this short cut," said the shark, pointing to his open mouth, "you'll save yourself a lot of time."
>
> "Gee, thanks," said the sea horse, and zoomed off into the interior of the shark, and was never found again.

The moral of the fable is: if you're not sure where you're going, you're liable to end up somewhere else.

10 mins

Step 3: Asking the right questions

Start a closer examination of the different research steps by providing a realistic example of the type of observation that prompts research questions among planners and providers. One example on reproductive tract infections (RTIs) is given below, but you may select an example that is more relevant to your setting.

What to cover in your input

Example: in a rural health centre, medical officers notice that the number of women presenting with RTIs has increased. They would like to know why.

In the example, the health professionals suspect that there is a problem and want to know more. Specific research objectives can now be identified. Answering these questions will help us identify a suitable study design.

What is (are) the research question(s)?

For the example above, some of the research questions may be:

1. What is the magnitude of the increase in the number of women presenting with symptoms of RTIs?
2. What accounts for this increase? Is it because more women are now coming to this health centre (as opposed to not seeking medical care or seeking traditional health care) or is it that the incidence and prevalence of RTIs have increased?
3. Are there differences in the above for different groups of women, for example by demographic characteristics such as age, marital status and parity; and by social class, race, ethnicity and place of residence?

What kind of evidence would answer these questions?

The kind of evidence that will answer these questions includes:

- the number of women presenting with symptoms of RTIs at this health centre each month, starting with the present and going back several months (if possible, one or two years)
- the health seeking behaviour of women with RTIs – looking at current as well as past episodes of RTIs
- the reasons for changes in health seeking behaviour (if relevant)
- it may be important to look for data on different groups of women: for example by demographic characteristics such as age, marital status and parity; and by social class, race, ethnicity and place of residence.

What existing evidence will answer these questions?

The first question may be answered with existing evidence – data from the health records of the health centre.

What type of new evidence is needed?

To answer the second question, new evidence is needed.

Step 4: Study design (10 mins)

Proceed to a brief input on study design.

The study design is determined by:

- the state of knowledge of the problem
- the type of research questions.

Put up the **overhead** of this table and explain the different types of study designs. (Refer to Handout 1 for more information on study designs.)

Overview of study designs

State of knowledge	Type of research question	Type of study design
Knowing that a problem exists, but knowing little about its characteristics	What is the nature of the problem? What is the magnitude? Who is affected? How do affected people behave? How do affected people perceive the problem?	Descriptive, quantitative and/or qualitative
Suspecting that certain factors contribute to the problem	Are certain factors associated with the problem? What are the processes through which these factors contribute to the problem?	Analytical, quantitative Qualitative
We know that certain factors are associated with the problem. We want to establish the extent to which a particular factor causes or contributes to the problem	What is the cause of the problem? Will the removal/addition of a particular factor reduce the problem? (e.g. stopping smoking/introducing iron supplementation)	Experimental or quasi-experimental Experimental or quasi-experimental: quantitative and/or qualitative
We have sufficient knowledge about cause to develop an intervention that would prevent, control, or solve the problem	What is the effect of the particular intervention? (e.g. a training programme, treatment with a new drug)	

Source: Varkevisser CM et al. *Designing and conducting health systems research projects.* International Development Research Centre Canada. Health Systems Research Training Series, volume 2, part 1. Ottawa, IDRC, 1991:118.

Different types of studies

A descriptive study involves the systematic collection and/or presentation of data to give a clear picture of a particular situation.

An analytical study attempts to establish cause or risk factors for certain problems. This is done by comparing two or more groups, some of which have or develop the problem and some of which do not.

In an experimental study women and men are randomly allocated to at least two groups. One group is subjected to an intervention while the other group(s) is not. The effect of the intervention on the problem is determined by comparing the two groups. For example, women with iron deficiency anaemia are assigned to two groups, one given iron supplementation and the other not. The group which has experienced the intervention is called the experimental group, and the second group is called the control group. After a certain time period, the anaemia status of both groups of women is checked again, and the effect of iron supplementation is ascertained. In the example above, when the assignment to the two groups is not random but one group has experienced an intervention and the other group has not, the study design is called quasi-experimental.

A pre-experimental study: If instead of comparing two groups, the same group is studied before and after the intervention, this is called a before-and-after (or pre-experimental) study. It is important to note that in large scale studies there are many factors besides the intervention itself that can impact on the outcome, and therefore data should be interpreted with caution. It is always advisable to use a control group wherever feasible.

Qualitative: When questions such as perceptions of the problem, ways in which it is experienced by those affected, and the processes through which various factors impact upon a problem are being addressed, the study design used is qualitative.

In the example of the RTI study we have been considering, to answer questions regarding the health seeking behaviour of women and reasons for changes, if any, the study design we would choose is descriptive and could involve both a quantitative and a qualitative component. This is because the research question aims to understand more about the nature of the problem.

Note: These are only examples of possible study designs for various kinds of research problems. There are no hard and fast rules. It is most important to ensure that the study design will address the research objectives.

10 mins

Step 5: The study population

The next step after the study design is to select the study population. The study population is the group of people or units from which we draw our sample. It must be defined precisely in terms of age, sex, time, and so on. The study unit is each unit of the sample selected from the study population.

Overhead Illustrate with a few examples:

Research questions, the study population and the study unit

Research question	Study population	Study unit
Is malnutrition related to weaning in district X?	All children aged 6–24 months in district X	One child aged 6–24 months in district X
What happened to women who had abnormal pap smears in hospital Y in 1999?	Patient files of all women who had an abnormal pap smear in hospital Y in 1999	One file of a patient with an abnormal pap smear in hospital Y in 1999
What is the sexual experience among 9th graders at school Z?	All grade 9 students at school Z	One grade 9 student at school Z

Going back to the RTI study example, the study population would consist of all women presenting at the rural health centre with symptoms of RTIs during a specified time period. Symptoms of RTIs would have to be defined, and the study population specified in terms of "women presenting in health centre A, during month B, with symptoms a, b or c".

The sample must be representative of the study population, and the sample size must be determined scientifically to make sure that the evidence is valid and generalizable. (Note that this session will not go into details of sampling.)

The best way of making sure that the sample represents the population is when each person in the wider population has a known and equal chance of being selected into the study. This is called random sampling, and it means that people were selected on the basis of chance.

Deciding whether a study population was big enough to generate meaningful evidence is not easy, but look to see whether the investigators based their design on a "sample size" calculation. When attempting to plan new studies, get advice on determining the correct sample size, as many studies are too small to generate reliable or useful results.

How generalizable is the evidence?

When reviewing evidence, always ask whether the sampling scheme that was chosen for the study allows you to generalize the results to the group you are concerned with.

If the evidence was gathered in another country, in a different type of health service or social setting, is there any reason to think the evidence may not apply to the group you are concerned with?

In the past, many United States clinical trials were conducted on men, because women's monthly cycles were thought to make drug studies more difficult. Data on new drug effects were generalized to women, despite the fact that no women had been sampled.

United States federal legislation passed in the late eighties made it mandatory that both women and men be included in the study of any drugs that both sexes might use.

10 mins

Step 6: Integrating a gender and rights perspective into health research

Integrating a gender and rights perspective means incorporating the following concerns, even at the stage of setting the research agenda:

- In what ways are rights being promoted and how are women or men likely to benefit from this research?
- Are there gender barriers that will introduce bias, or otherwise interfere with the objective outcome(s) of this research?
- Are there any rights that are likely to be violated when conducting this research?

In the RTI example, gender and rights awareness is reflected in the recognition, when framing the research question, that women may not always access medical care even when they have problems. Hence, an unbiased study of women's health seeking for RTIs will have to account for gender/power differences in women's lives. Research methods (specifically data collection) would ensure that women in the study population feel comfortable and are able to articulate their responses – for example, by engaging female interviewers, ensuring privacy and confidentiality, allowing for open-ended responses, using local terminology for symptoms, and so on. The analysis and interpretation of results will also bear in mind how gender and rights impact on RTIs. For example, is a recurrence of infection related to non-use of condoms? Would this be related to women's employment or educational status (used as an indicator of women's status)?

Refer participants back to Session 3 of the Rights Module, which examined the rights implications of public health policies and programmes.

Remind participants also of Session 5 of the Gender Module, where we did a gender analysis of health problems. Gendered health research would, wherever relevant, ask questions about whether and how gender impacts on the health problem in question.

Put up the following **overhead.**

Some main points from the Gender Module, Session 5: Linking gender and health

Questions to ask about the role of gender in a specific health problem

For health problems affecting women and men:
- Are there different risk factors for women and men?
- Do the roles society prescribes for women and men account for differences in the risk factors?
- What are the barriers/obstacles to obtaining treatment for the condition? Are the barriers different for women and men?
- Are there differences for women and men in the severity of consequences? What accounts for these differences?
- Are there different responses from the health sector?
- Are there different responses from society at large?

For health problems which are sex-specific:
- Are the risk factors related to gender roles and or norms?
- Are barriers to obtaining treatment, health seeking behaviour, severity of consequences, responses from the health sector and from the society influenced by the role society prescribes for men and women?

Questions to ask about rights:

- Consider every right that may be violated or promoted by this intervention
- Think through how exactly the right is being impacted upon in the short term as well as in the long term.

40 mins

Activity 2: Discussion about research problems

Distribute Handout 2 and put it up as an **overhead.**

Read each problem aloud, and ask for responses to the following questions:

- What is/are the research questions?
- What existing evidence would answer these?
- What type of new evidence do you need?
- What kind of research methodology is needed?
- Who/what would the study population be?
- How will gender/rights issues be addressed in this study?

Questions for undertaking research

Write out responses to each of these questions on a flip chart(s) in table form:

What is/are the research questions?	What existing evidence would answer these?	What type of new evidence do you need?	What kind of research methodology is needed?	Who/what would be the study population?	How will gender and rights be addressed in the study?

What to cover in the discussion on Problem 1 in Handout 2

The research questions

- Has the number of newborns of very low birth weight increased?
- If yes, is this increase in the proportion of deliveries which result in the birth of infants of very low birth weight? Or is the increase in numbers the reflection of an increase in the number of deliveries (the proportion is the same)?
- Is there a difference in the social and economic status of women delivering low birth weight babies, and women delivering babies of normal birth weight?

Definitions

We would have to define what we mean by "very low birth weight", specifying this as below xxx grams at birth (usually 1500 grams), and the "socio-economic status" in terms of number of years of education, income levels, and so on.

What kind of evidence is needed?

- the number of live births in this hospital, starting from the present and going back a few years
- the number of live births with a birth weight below 1500 grams during the same period
- the socio-economic status of the mothers.

Most of the information above may be available from hospital records. In that case, no new data collection is needed.

Study design

The study design to be used here is descriptive and quantitative.

Sample

The sample population consists of hospital records of deliveries in that hospital for the past x years. The sample unit is one record of a delivery.

Our gender and rights perspective

How would we bring a gender and rights perspective to this study? One way would be to reframe the question on the characteristics of women giving birth to infants of low birth weight to include not the income level of the household but an indicator of the woman's access to resources, as well as her education and other factors associated with gender based discrimination. Also, because of the known relationship between maternal health and nutritional status and low birth weight of infants, and because there are gendered differences in women's health and nutritional status, these could also be included as factors to examine. There is also evidence of an association between domestic violence and low birth weight which could be explored. Other confounding variables such as smoking and substance abuse will also need to be examined.

Main points for closing this session

Precision

Identifying sound research objectives needs you to clearly specify the research question you want to address. You must generate a precise list of the types of evidence needed to answer that question. There is a temptation to ask questions that are vague, or to have many objectives for one study. The correct research design is more likely to be chosen if the objectives are clear, and expressed in measurable terms.

Don't overlook potential evidence

Evidence is often at hand, and overlooked (Problems 1 and 4). For example, examining the duty rota for students for the past month or two to see if there are systematic patterns by gender may provide the hard evidence needed to establish whether or not women students are indeed being given extra menial duties, and being made to do the most demanding work.

A range of techniques

Operations research (Problem 2) includes a wide array of techniques for determining what is actually going on in a service. Mystery clients, observations, and exit interviews with clients can all provide insights into client-provider interactions. Focus group discussions can quickly draw out public fears and perceptions about services and products (see Session 7, Handout 4). Provider biases, if they are widespread, require gathering evidence on their sources of information (training, information-education and communication) and commodity suppliers.

Good baseline data

Collecting impact data (Problem 3) requires generating good, representative baseline data before the intervention. If the overall case load in the service is high, baseline cases over one to two months may be adequate, but a low case load in the baseline period will make it harder to detect a positive change after the intervention (even if it is real!).

The impact of outside factors

When measuring the impact of interventions (Problem 3), it is necessary to anticipate other factors that could change your outcome measure (in this case, STI rates) during the intervention period (for example, an increase in truck stop sex trade, a seasonal return of urban workers, and so on). These should be monitored during the study to ensure that outside events don't interfere with your ability to measure changes. (Refer to the note on before-and-after studies in Handout 1.)

Session developed by Nana Kgosidintsi, Rachel Snow and Khin San Tint

Handout

1 Study designs

Study designs from Varkevisser C. M. et al. *Designing and conducting health systems research projects.* International Development Research Centre Canada. Health Systems Research Training Series, volume 2, Part 1. Ottawa, IDRC, 1991:118-129.

1. Introduction

Depending on the existing state of knowledge about a problem that is being studied, different types of questions may be asked that require different study designs. Some examples are given in Table 9.1.

Table 9.1. Research questions and study designs

State of knowledge of the problem	Type of research questions	Type of study design
Knowing that a problem exists, but knowing little about its characteristics or possible causes	What is the nature/magnitude of the problem? Who is affected? How do the affected people behave? What do they know, believe, think about the problem?	Exploratory studies or descriptive studies: Descriptive case studies Cross-sectional surveys
Suspecting that certain factors contribute to the problem	Are certain factors indeed associated with the problem? (e.g., is lack of preschool education related to low school performance? Is low fibre diet related to carcinoma of the large intestine?)	Analytical (comparative) studies: Cross-sectional comparative studies Case-control studies Cohort studies
Having established that certain factors are associated with the problem; desiring to establish the extent to which a particular factor causes or contributes to the problem	What is the cause of the problem? Experimental or will the removal of a particular factor prevent or reduce the problem? (e.g., stopping smoking, providing safe water)	Cohort studies Quasiexperimental study designs
Having sufficient knowledge about cause to develop and assess an intervention that would prevent, control, or solve the problem	What is the effect of a particular intervention/strategy? (e.g., treating with a particular drug, being exposed to a certain type of health education) Which of two alternative strategies gives better results? Are the results in proportion to time/money spent?	Experimental or quasiexperimental study designs

The type of study design chosen depends on:

- **The type of problem,**
- **The knowledge already available about the problem, and**
- **The resources available for the study.**

When investigating health-management problems, such as overcrowding in a hospital out-patient department or shortage of drugs at PHC level, a good description of the problem and identification of major contributing factors often provides enough information to take action.

When exploring more complicated management problems and many health problems, we usually want to go further and determine the extent to which one or several independent variables contributes to the problem (for example, the contribution of low-fibre diet to cancer of the large intestine). For these types of problems, more rigorous analytical or quasi-experimental studies will have to be conducted before we decide on appropriate interventions.

2. Overview of study types

Several classifications of study types are possible, depending on what research strategies are used. Usually a combination of research strategies is used, including:

- Nonintervention studies in which the researcher just describes and analyzes researchable objects or situations but does not intervene; and
- Intervention studies in which the researcher manipulates objects or situations and measures the outcome of his manipulations (e.g. by implementing intensive health education and measuring the improvement in immunization rates).

Nonintervention studies

We will first concentrate on nonintervention studies and their use in Health Systems Research. We will discuss:

- Exploratory studies,
- Descriptive studies, and
- Comparative (analytical) studies.

1. Exploratory studies

An EXPLORATORY STUDY is a small-scale study of relatively short duration, which is carried out when little is known about a situation or a problem.

For example

A national Acquired Immunodeficiency Syndrome (AIDS) control program wishes to establish counseling services for Human Immunodeficiency Virus (HIV) positive and AIDS patients, but lacks information on specific needs patients have for support. To explore these needs, a number of in-depth interviews are held with various categories of patients (males, females, married, single) and with some counsellors working on a program that is already under way.

When doing exploratory studies we describe the needs of various categories of patients and the possibilities for action. We may want to go further and try to explain the differences we observe (e.g., in the needs of male and female AIDS patients) or to identify causes of problems. Then we will need to compare groups.

Note Comparison is a fundamental research strategy to identify variables that help explain why one group of persons or objects differs from another.

In Health Systems Research, small-scale studies that compare extreme groups are very useful for detecting management problems. We could, for example, compare:

- Two health centres that are functioning well and two that do not function satisfactorily to detect the possible reasons for bottlenecks in the functioning of the peripheral services;
- One community with high and another with low participation in health activities to identify factors that contribute to community participation;
- 40 mothers who delivered in a maternity ward and 40 who delivered at home to find reasons for the low percentage of supervised deliveries.

Exploratory studies gain in explanatory value if we approach the problem from different angles at the same time. In the study that is looking for causes of the low percentage of supervised deliveries, it may be very useful to include observations and interviews with health staff in the maternity centres that should serve the mothers in question and interviews with their supervisors, as well as with the mothers themselves. In this manner, information from different independent sources can be cross-checked.

For some management problems, such a "rapid appraisal" may provide sufficient information to take action. Otherwise, a larger, more rigorous comparative study will have to be developed to test differences between groups with respect to various independent variables.

Note If the problem and its contributing factors are not well defined (see Module 8 group work) it is always advisable to do an exploratory study before embarking on a large-scale descriptive or comparative study.

2. Descriptive studies

A DESCRIPTIVE STUDY involves the systematic collection and presentation of data to give a clear picture of a particular situation.

Descriptive studies can be carried out on a small or large scale.

Descriptive case studies describe in-depth the characteristics of one or a limited number of "cases." A case may be, for example, a patient, a health centre, or a village. Such a study can provide useful insight into a problem. Case studies are common in social sciences, management sciences, and clinical medicine. For example, in clinical medicine the characteristics of a hitherto unrecognized illness may be documented as a case study. This is often the first step toward building up a clinical picture of that illness. Descriptive case studies that lead to the construction of theories may be very time consuming. If they are of short duration, you may as well call them explanatory studies.

However, if one wishes to test whether the findings pertain to a larger population, a more extensive, cross-sectional survey has to be designed.

Cross-sectional surveys aim at quantifying the distribution of certain variables in a study population at one point of time. They may cover, for example:

- **Physical characteristics** of people, materials, or the environment, as in
  - prevalence surveys (of bilharzia, leprosy), or
  - evaluation of coverage (of immunization, latrines, etc,),
- **Socioeconomic characteristics** of people, such as their age, education, marital status, number of children, and income,
- The **behaviour** of people and the **knowledge, attitudes, beliefs, and opinions** that may help to explain that behaviour (KAP studies), or
- **Events** that occurred in the population.

Cross-sectional surveys cover a sample of the population. If a cross-sectional study covers the total population it is called a **census.**

A cross-sectional survey may be repeated to measure changes over time in the characteristics that were studied.

The surveys may be very **large,** with hundreds or even thousands of study units. In these cases only a **limited number of variables** will usually be included, to avoid problems with analysis and report writing. If cross-sectional surveys are **smaller** they can be **more complex.** They may include all the elements just mentioned. Small surveys can reveal interesting associations between certain variables, e.g., between having leprosy and socioeconomic status, sex, and education.

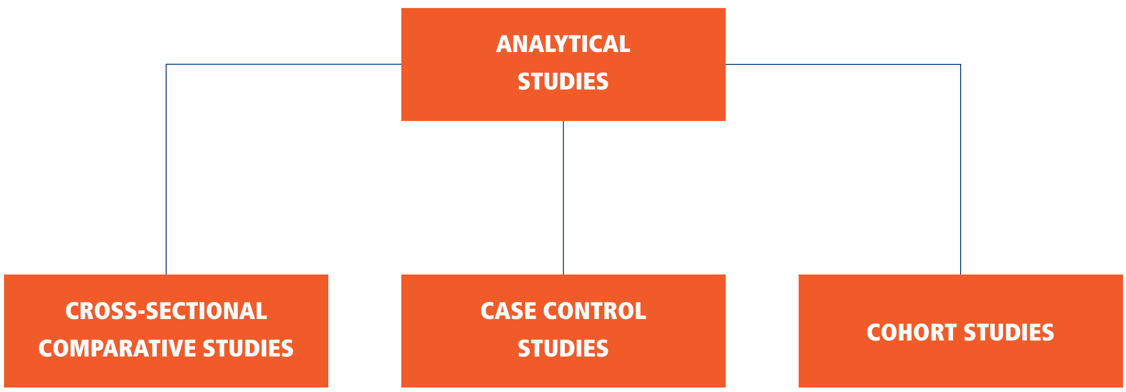
Researchers often go further and will combine a DESCRIPTION of the study population with a COMPARISON of a number of groups within that population (see below). Such combinations are very common and thus the distinctions between descriptive and comparative studies are sometimes quite fuzzy.

3. Comparative or analytical studies

*An ANALYTICAL STUDY attempts to establish **causes or risk factors** for certain problems. This is done by comparing two or more groups some of which have or develop the problem and some of which have not.*

Three commonly used types of analytical studies are discussed here.

Figure 9.1. Types of analytical studies



Cross-sectional comparative studies

Many cross-sectional surveys focus on comparing **as well as** describing groups.

For example A survey on malnutrition may wish to establish:

- The percentage of malnourished children in a certain population;
- Socioeconomic, physical, political variables that influence the availability of food;
- Feeding practices; and
- The knowledge, beliefs, and opinions that influence these practices.

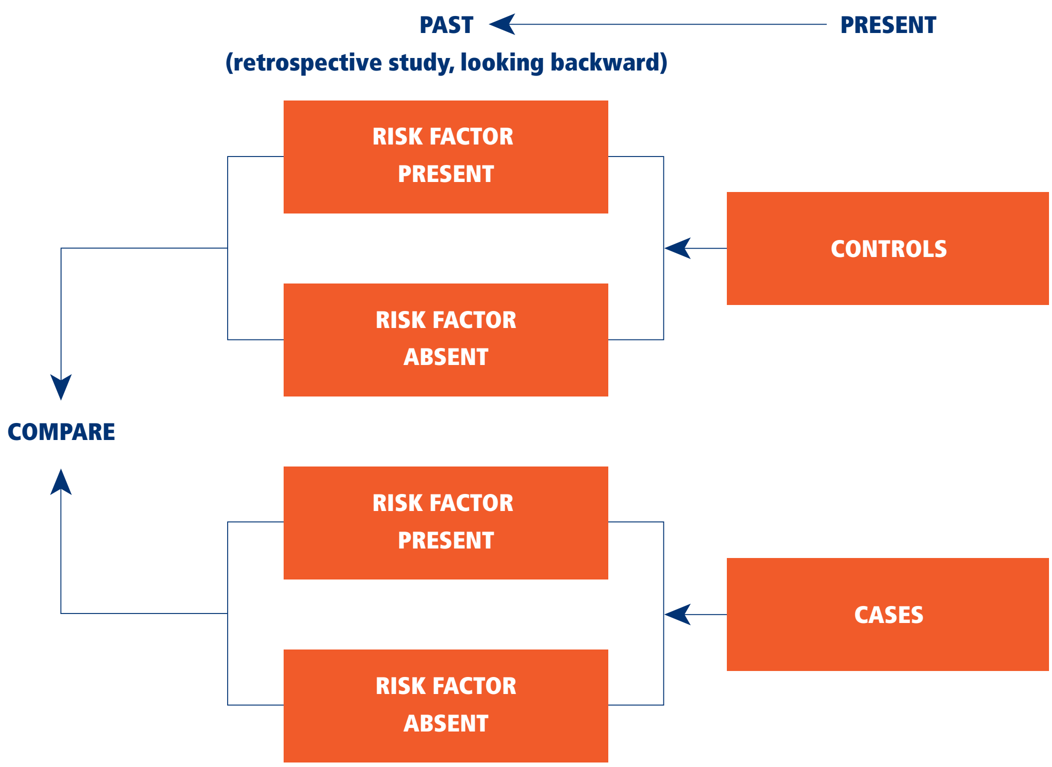
1. The researcher will not only describe these variables but, by comparing malnourished and well nourished children, he or she will try to determine which socioeconomic, behavioural, and other independent variables have contributed to malnutrition.

In any comparative study, one has to watch out for **confounding** or **intervening** variables. (Please refer to Module 8 for examples and discussion.)

Case-control studies

In a CASE-CONTROL STUDY, the investigator compares one group among whom a problem is present (e.g. malnutrition) with another group, called a control or comparison group, where the problem is absent to find out what factors have contributed to the problem.

Figure 9.2. Diagram of a case control study



Adapted from Holland, W.W. et al. 1985. *Oxford textbook of public health, volume 3: invesetigative methods in public health.* Oxford University Press, Oxford, England.

For example In a study of the causes of neonatal death the investigator first selects his "cases" (children who died within the first month of life) and "controls" (children who survived their first month of life). He then interviews their mothers to compare the history of these two groups of children, to determine whether certain risk factors are more prevalent among the children who died than among those who survived.

As with a cross-sectional comparative study, the researcher has to control for confounding variables. In case-control studies, this may be done to some extent beforehand, by matching the groups for expected confounding variables. Matching means taking care that the cases and controls are similar with respect to the distribution of one or more potentially confounding variables.

For example In the study on possible causes of neonatal death we would like to match the mothers for age (as this factor could influence death), as well as for other socioeconomic variables (education, marital status, and economic status). We might select, for each mother of a baby that died within a month after birth, a mother of exactly the same age whose baby did not die. We might also match the groups on environment and select "controls" from the same village as "cases".

Note Although ideally a researcher would like to match the cases and controls for all variables except the ones he is testing as risk factors or "causes" for the problem under study, this is in practice impossible, even inadvisable. (You might "match away" variables you are interested in.) Case-control studies, therefore, use stratification as well as matching to control for confounding variables.

Cohort studies

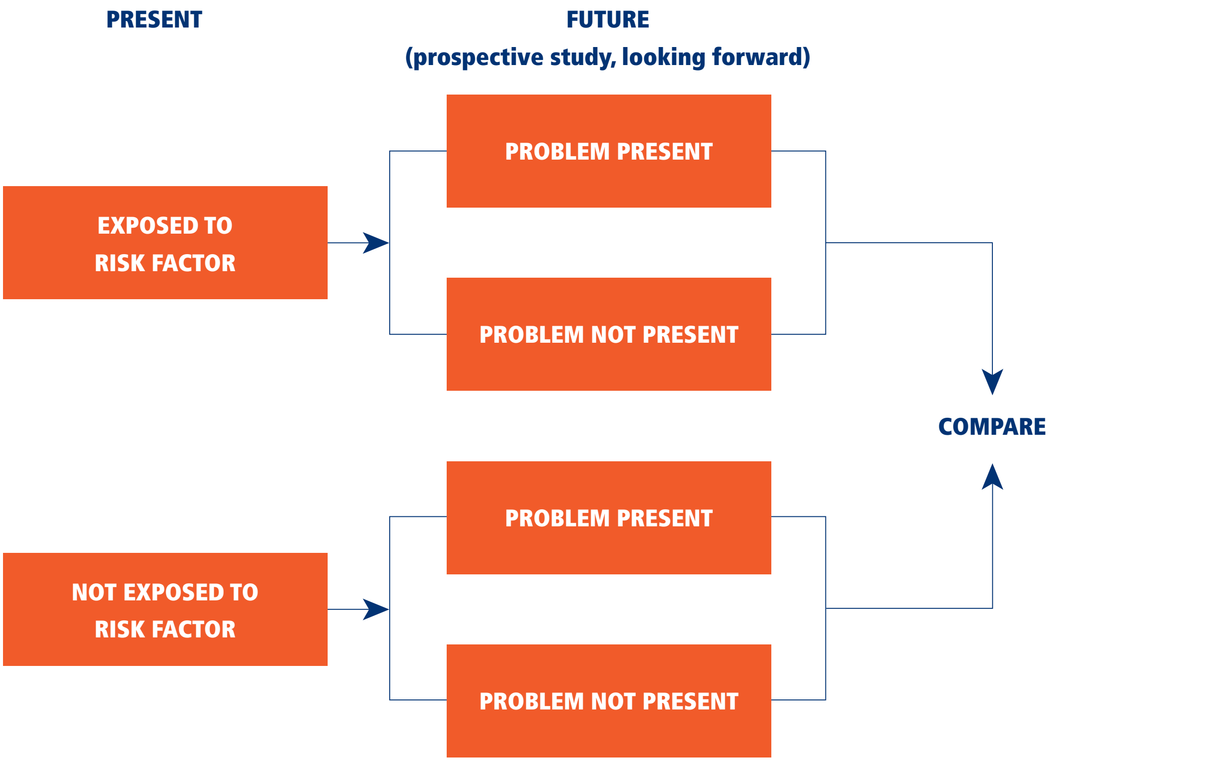
In a COHORT STUDY, a group of individuals that is exposed to a risk factor (study group) is compared with a group of individuals not exposed to the risk factor (control group). The researcher follows both groups over time and compares the occurrence of the problem that he or she expects to be related to the risk factor in the two groups to determine whether a greater proportion of those with the risk factor are indeed affected.

A well known example of a cohort study is the Framingham study of smokers and nonsmokers that was conducted to determine the importance of smoking as a risk factor for developing lung cancer.

A study may start with one large cohort. After the cohort is selected, the researchers may then determine who is exposed to the risk factor (e.g. smoking) and who is not, and follow the two groups over time to determine whether the study group develops a higher prevalence of lung cancer than the control group. If it is not possible to select a cohort and divide it into a study group and a control group, two cohorts may be chosen, one in which the risk factor is present (study group) and one in which it is absent (control group). In all other respects the two groups should be as alike as possible.

The control group should be selected at the same time as the study group, and both should be followed with the same intensity.

Figure 9.3. Diagram of a cohort study



Adapted from Holland et al. 1985.

Uses and limitations of different types of analytical studies

You may use any of the three types of analytical studies (cross-sectional comparison, case-control, or cohort) to investigate possible causes of a problem.

For example

If you assume there is a causal relationship between the use of a certain water source and the incidence of diarrhea among children under 5 years of age in a village with different water sources:

- You can select a group of children under 5 years and check at regular intervals (e.g. every 2 weeks) whether the children have had diarrhea and how serious it was. Children using the suspected source and those using other sources of water supply will be compared with regard to the incidence of diarrhea (cohort study).
- You can also conduct a case-control study. For example, you may compare children who present themselves at a health centre with diarrhea (cases) during a particular period of time with children presenting themselves with other complaints of roughly the same severity, for example acute respiratory infections (controls) during the same time, and determine which source of drinking water they had used.
- In a cross-sectional comparative study, you could interview mothers to determine how often their children have had diarrhea during, for example, the past month, obtain information on their source of drinking water, and compare the source of drinking water of children who did and did not have diarrhea.

Cross-sectional comparative studies or case-control studies are usually preferred to cohort studies for financial and practical reasons.

Cross-sectional comparative studies and case-control studies are relatively quick and inexpensive to undertake. With cross-sectional comparative studies, however, the number of stratifications one can make is limited by the size of the study. The major problem with case-control studies is the selection of appropriate control groups. The matching of cases and controls has to be done with care. Cohort studies are the only sure way to establish causal relationships. However, they take longer than case-control studies and are labour intensive and, therefore, expensive. The major problems are usually related to the identification of all cases in a study population especially if the problem has a low incidence, and to the inability to follow up all persons included in the study over a number of years because of population movement.

Intervention studies

In intervention studies, the researcher manipulates a situation and measures the effects of this manipulation. Usually (but not always) two groups are compared, one in which the intervention takes place (e.g. treatment with a certain drug) and another group that remains "untouched" (e.g. treatment with a placebo).

The two categories of intervention studies are:

- experimental studies and
- quasi experimental studies.

1. Experimental studies

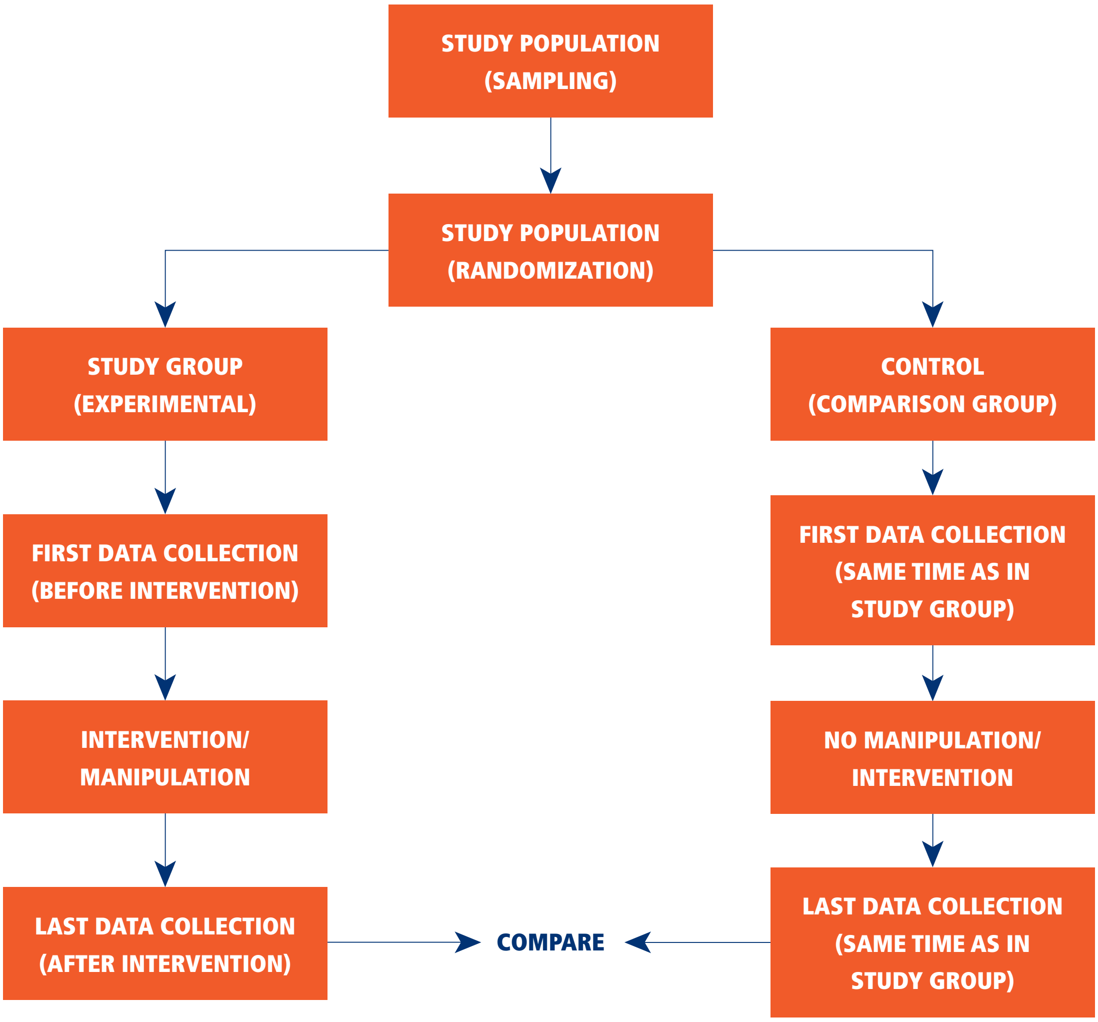
An experimental design is the only type of study design that can actually prove causation.

In an EXPERIMENTAL STUDY, individuals are randomly allocated to at least two groups. One group is subject to an intervention, or experiment, while the other group(s) is not. The outcome of the intervention (effect of the intervention on the dependent variable/problem) is obtained by comparing the two groups.

The classical experimental study design has three characteristics:

- **Manipulation** - the researcher does something to one group of subjects in the study.
- **Control** - the researcher introduces one or more control group(s) to compare with the experimental group.
- **Randomization** - the researcher takes care to randomly assign subjects to the control and experimental groups. (Each subject is given an equal chance of being assigned to either group, e.g., by assigning them numbers and "blindly" selecting the numbers for each group.)

Figure 9.4. Diagram of an experimental study



Note The strength of experimental studies is that by randomization the researcher eliminates the effect of confounding variables.

A number of experimental study designs have been developed. These are widely used in laboratory settings and also in clinical settings. For ethical reasons, the opportunities for experiments involving human subjects are restricted. However, randomized control trials of new drugs are common and this design is often considered for the testing of the efficacy of other interventions. Feasibility as well as ethics must be seriously considered in choosing this design.

For example A researcher plans to study the effect of a new drug. (The drug has already been tested extensively on animals and has been approved for trial use.) He plans to include 300 patients in the study who are currently receiving a standard treatment for the condition that the new drug has been designed to alleviate. He explains the study to the patients asking their consent to be divided into two groups on a random basis. One group will receive the experimental drug while the other group will continue to receive the standard treatment. He makes sure that the medications are disguised and labelled in such a manner that neither the research assistant administering them nor the patient knows which drug is used. (This is called a "double blind" experiment.)

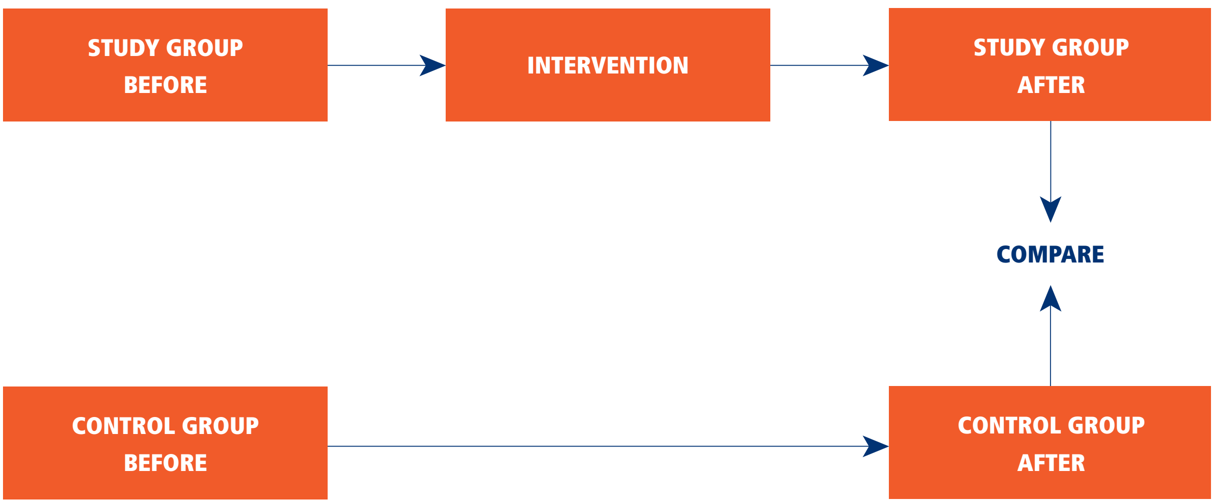
At community level, where Health Systems Research is frequently undertaken, we experience not only ethical but also practical problems in carrying out experimental studies. In real life settings, it is often impossible to assign persons at random to two groups, or to maintain a control group. Therefore, experimental research designs may have to be replaced by quasi experimental designs.

2. Quasi experimental studies

In a QUASI EXPERIMENTAL STUDY, at least one characteristic of a true experiment is missing, either randomization or the use of a separate control group. A quasiexperimental study, however, always includes manipulation of an independent variable that serves as the intervention.

One of the most common quasiexperimental designs uses two (or more) groups, one of which serves as a control group in which no intervention takes place. Both groups are observed before as well as after the intervention, to test if the intervention has made any difference. The subjects in the two groups (study and control groups) have not been randomly assigned.

Figure 9.5. Diagram of a quasi experimental design with two groups

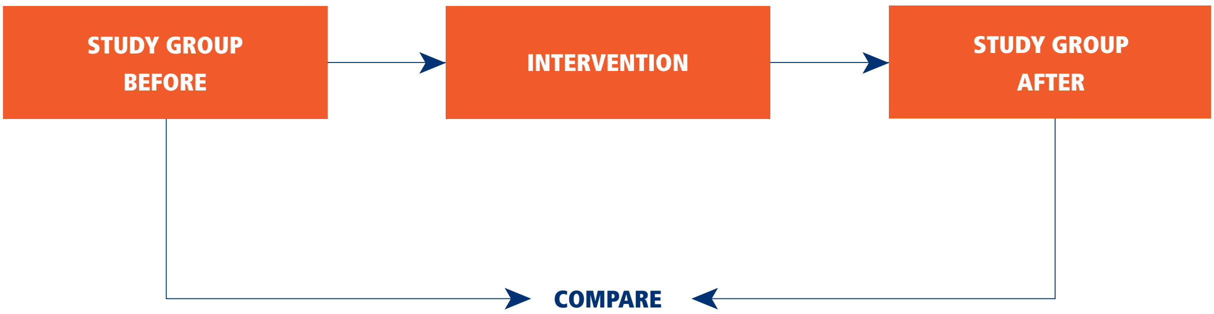


Example of a quasi experimental study

A researcher plans to study the effects of health education on the level of participation of a village population in an immunization campaign. She decides to select one village in which health education sessions on immunization will be given and another village that will not receive health education to serve as a control. The immunization campaign will be carried out in the same manner in both villages. A survey will then be undertaken to determine if immunization coverage in the village where health education was introduced before the campaign is significantly different from coverage in the "control" village which did not receive health education. (Note: The study is quasi experimental because the subjects were not assigned to the control or experimental groups on a random basis.)

Another type of design that is often chosen because it is quite easy to set up uses only one group in which an intervention is carried out. The situation is analyzed before and after the intervention to test if there is any difference in the observed problem. This is called a "before-after" study. This design is considered a "pre-experimental" design rather than quasi experimental, because it involves neither randomization nor the use of a control group.

Figure 9.6. Diagram of a before-after study



Example of a before-after study

The outpatient clinic of hospital X is extremely crowded. Waiting times of over 5 hours for patients before they are attended to are not uncommon. The hospital management has a study carried out to analyze the bottlenecks and implements most of the recommendations made. Three months later, another study is done to check to what extent the bottlenecks have been solved and where further action is necessary.

This design is often used for management problems that pertain to one single unit (hospital, school, village). However, if the problems occur at a larger scale or if they might be influenced by other factors apart from the intervention during the trial, it is highly recommended that the design include both a study and a control group.

In the trial with health education on immunization, for example, K would have been quite risky to work without a control group. Outside events (such as a health education campaign on immunization by radio or other mass media) might have led to improved knowledge on immunization in both the study group and the control group. (Note: The immunization campaign by radio provides a so-called "rival explanation" for your results.) If you had had just a study group and no control, you might have concluded erroneously that all of the increase was due to your own intervention.

Handout

2 Examples of problems addressed by health research

Problem 1

In a large tertiary obstetric service the health professionals suspect that the number of newborns of very low birth weight is increasing. The service wants to know if this is true, and if so to have a better understanding of the social and economic situation of the women who are delivering low birth weight babies. How can you answer these questions?

Problem 2

The state family planning service supplies free oral pills, IUDs, injections, condoms and both male and female sterilization. However, even though overall contraceptive use is at 40 per cent, almost 90 per cent of new users in the last 24 months have taken IUDs. You suspect there may be extensive provider bias, incentives or rumours that are leading so many clients to take one method. How can you determine what is going on?

Problem 3

You are about to introduce a new counselling service for men in your STD clinics, which focuses on preventive behaviours, especially the use of condoms. This is a pilot project. The new service has cost a lot, and in order to justify its expense you will need evidence demonstrating whether the new service has any positive health impact. How can you generate the evidence to evaluate the new service?

Problem 4

You are appointed dean of the medical faculty. After a year you notice that the female medical students seem to do well in the classroom, but quickly fall to the bottom of the class once clinical work begins. In a given month, three women students complain to you that the hospital staff creates obstacles for women students by giving them extra menial duties, appointing them to do the most demanding work, and even humiliating them during open rounds. After two days observing in the hospital, you agree this seems to be the case. What kind of evidence may help you address this problem?

SESSION 3

Ethical issues in reproductive health research

What participants should get out of the session

Participants will:

- be acquainted with the principles of ethics in research, focusing on reproductive health
- have an overview of international ethical guidelines for conducting research
- have debated key ethical dilemmas in reproductive health research from a gender perspective.

2 hrs 30 mins

2 hours and 30 minutes

Materials

- Lecture notes for the facilitator: "Ethical issues in reproductive health research"
- Handout: "Ethical and appropriate research"

- overheads or Powerpoint presentation based on Lecture notes for the facilitator
- overhead: "Ethics and human rights", on p.246
- 8 pieces of paper for the debate: 4 marked "For quinacrine research" and 4 marked "Against quinacrine research"; some blank pieces of paper, following instructions on p.246

Readings for the facilitator

1. Council for International Organizations of Medical Sciences (CIOMS). *International ethical guidelines for biomedical research involving human subjects.* Geneva, CIOMS, 1993. Available online at: www.who.int/dsa/cat98/ethic8.htm#International Ethical Guidelines for Biomedical Research Involving Human Subjects

Readings for the participants

1. Berer M. The quinacrine controversy continues. *Reproductive Health Matters,* 1995, **6:**142–146.

2. Pollack AE, Carigan CS. The use of quinacrine pellets for non-surgical female sterilization. *Reproductive Health Matters,* 1993, **2:**119–120.

How to run the session

This session consists of a presentation on ethical principles in research and the current international guidelines that govern research, particularly in reproductive health. It also includes gender guidelines for conducting research. This is followed by a debate on the ethics of a controversial reproductive health research issue, where you ask participants to take positions and defend them. In this manual, the case of testing quinacrine is used, but another topic may be used, as long as there are clear arguments both for and against the issue, with adequate information to support both positions, but where the ethics of the intervention can be questioned. The debate is followed by a discussion which should link the issues raised in the debate with the ethical and gender guidelines.

Give the handout to participants the day before and instruct them to go through the readings for this session which are in their Course Files. This will allow them some time for becoming familiar with the issues.

1 hr

Activity 1: Introducing ethical principles

This is an interactive input session. Ensure that the concepts – which can seem quite theoretical – are clear to everyone. Encourage discussion on key points by asking participants for concrete examples.

30 mins

Step 1: Your lecture

Prepare and present a lecture (aided by Powerpoint or **overheads**) containing the key points in the lecture notes, including:

- background to the development of universal ethical principles and standards
- key ethical principles elaborated in the Declaration of Helsinki: respect for persons, beneficence and justice
- informed consent as a key issue in medical research
- gender considerations in research.

20 mins

Step 2: Some questions

Ask participants for examples of research where:

- some of the ethical principles may not be adhered to
- gender equality would not be promoted in health and health care
- it would make a difference whether the researchers are women or men.

10 mins

Step 3: The link between ethics and rights

Put up the following **overhead** and go over its contents.

Ethics and human rights

Source: Mann JM, Medicine and public health, ethics and human rights. In: Mann JM, Gruskin S, Grodin MA, Annas GJ, eds. *Health and human rights: a reader.* New York, Routeledge, 1999:446.

"Ultimately, ethics and human rights derive from a set of quite similar, if not identical, core values … rather than seeing human rights and ethics as conflicting domains, it seems more appropriate to consider a continuum on which human rights is a language most useful for guiding societal-level analysis and work, while ethics is a language most useful for guiding individual behaviour … Thus, public health work requires both ethics applicable to the individual public health practitioner and a human rights framework to guide public health in its societal analysis and response."

The presentation and discussion are used as a basis for the debate that will follow, where participants can put this theory into practice.

1 hr 15 mins

Activity 2: The debate

10 mins

Step 1: Choosing the teams

Choose a way to appoint eight participants as speakers in the debate, four on each side. This could be done by having each participant choose a piece of folded paper from a hat. Four pieces of paper will be marked "For quinacrine research" and four will be marked "Against quinacrine research". The rest will be blank. The people who draw blank pieces will be the judges. One person (preferably an outsider) should be appointed as the debating arbiter. Give each team copies of the handout.

30 mins

Step 2: The rules of a debate

Ask if anyone can explain the rules of debating. If not, explain that one group of four people will defend the project concerning quinacrine research, and the other group will oppose it, on the basis of the information in the handout. Each group chooses the order of their speakers, each of whom will develop arguments to support the group's position. The first two speakers in each group have five minutes each to lay out their argument, and the second two speakers three minutes each. Speakers from each group alternate, so the groups should anticipate the main arguments that the other group will make in order for subsequent speakers to refute them. They are given a maximum of 30 minutes to prepare. During this time the judges are also given the handout and have an opportunity to discuss it before the debate.

35 mins

Step 3: Start the debate

You should keep strict time. The arbiter starts the process, inviting the first speaker from group 1 (in favour of the project) to begin. Next is the first speaker from group 2. Remember: the first two speakers in each group have five minutes each to lay out their arguments, and the second two speakers three minutes each.

When all eight speakers have presented their arguments, the arbiter then asks the judges to vote in favour of one group or the other. Whichever has the greater number of votes wins the debate.

25 mins

Activity 3: Discussion

Bring the group together again, and ask for a discussion of how the quinacrine research case relates to the ethical principles discussed earlier.

What to cover in the discussion

Respect for persons

Were the subjects going to be given full information about the research (refer to the box "Informed consent" in your lecture notes), such as the purpose, and the procedures? Is any inducement being made? Is there provision for keeping information confidential? Is the study population particularly vulnerable?

Beneficence

Is the scientific data adequate to demonstrate the safety of quinacrine for humans? What are the risks associated with quinacrine? What are the potential benefits? Do the benefits outweigh the risks? Have the previous research results been based on scientifically sound designs? Are there alternatives which are available as good as the proposed procedure?

Justice

What population group is the focus of the research? All categories of women, or only poor women? Is this ethical? Will the potential benefits and risks be distributed equitably at national and international levels?

Gender equity

Does the research address a demonstrated public health need expressed by women and/or men? This may be difficult to answer, but there may be some evidence of women's and men's desires concerning the kinds of contraceptive methods they need. Will the research promote equality between women and men? One way of tackling this question is to ask: would the discussion be the same if this were a method of male sterilization?

Why the proposed quinacrine research is unethical

Demonstrate, through the discussion of these questions, that the proposed quinacrine research is unethical from many points of view:

- The information given to subjects will be inadequate because it is based on flawed research.
- The benefits do not outweigh the risks because the product is suspected to be carcinogenic (cancer-causing).
- There is an (acceptable) alternative – mini-laparotomy, and also vasectomy, which is cheap and easy.
- The population being targeted is poor women, which calls into question the issues of both respect for persons and distributive justice.
- In a situation of high (or growing) HIV prevalence, promotion of female sterilization may take efforts away from promotion of protection against STIs and HIV and be detrimental to women in particular, thus reinforcing gender inequalities.

Session developed by Jane Cottingham

Lecture notes for the facilitator:

Ethical issues in reproductive health research

These notes provide you with the major content of the input in Activity 1 of this session. You may either use it as it is, elaborating on each of the points during discussion, or rework it to focus on the points you consider particularly pertinent to the group you are working with.

Universal ethical principles and standards

The development of universal ethical principles and standards for research began after the atrocities committed by the Nazis during World War II. In 1947, the *Nuremberg Code* was elaborated, to protect subjects of medical research. In 1966 the *International Covenant on Civil and Political Rights* included specific protection in Article 7: "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." The fundamental document in the field of ethics and biomedical research – the *Declaration of Helsinki* – was established in 1964, and all of our current principles guiding medical research are based on that. For instance, the *International ethical guidelines for biomedical research involving human subjects*, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization in 1993 are the main guidelines that WHO uses in conducting reproductive health research.

The key ethical principles elaborated in the *Declaration of Helsinki*

- Respect for persons

  This includes two fundamental ethical considerations:

  - respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination

  - protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.

- Beneficence

  This refers to the ethical obligation to maximize benefits and minimize harms and wrongs. This principle gives rise to norms requiring that the risks of research are reasonable in the light of the expected benefits, that the research design is sound, and that the investigators are competent both to conduct the research and to safeguard the welfare of the research subjects. Beneficence further forbids the deliberate infliction of harm on persons – sometimes called "non-maleficence" (do no harm).

- **Justice**
  This refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to her or him. In the ethics of research involving human subjects, the principle refers primarily to distributive justice, which requires the equitable distribution of both the burdens and the benefits of participation in research. Differences in distribution of burdens and benefits are justifiable only if they are based on morally relevant distinctions between persons. One such distinction is "vulnerability". This refers to a substantial incapacity to protect one's own interests because of impediments like the inability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provisions must be made for the protection of the rights and welfare of vulnerable persons.

Any of the above principles can be elaborated on in further detail (refer to the CIOMS guidelines). To make the connection with other parts of the course, especially the Health Systems Module (sessions dealing with client-provider interaction and the importance of information), select the issue of informed consent for further elaboration.

Informed consent

Informed consent is an important issue in medical research, particularly in the area of human reproduction. Historically, contraceptive research has raised many questions because of the concern that methods on trial might in fact cause infertility or affect in other ways people's abilities to reproduce, or may have been done without women's awareness or full information.

Informed consent

The key pieces of information needed to ensure that a potential research participant can make an informed decision (informed consent or dissent) are:

- the purpose of the research
- the procedures to be undertaken
- the foreseeable risks or discomforts
- the expected benefits to subjects or others
- appropriate alternatives if any
- how confidentiality will be maintained
- a statement that participation is voluntary and subjects have an option to withdraw at any time
- the availability of medical treatment or compensation in case of injury from participation.

If a research protocol does not demonstrate how this information will be given to research subjects, or if it is subsequently found that subjects did not receive this information, the research (and the research results) can be considered unethical.

Gender considerations

In addition to the ethical questions, a number of gender specific questions need to be considered, especially in relation to reproductive health research. Because women suffer the far greater burden of reproductive ill health, and because women, not men, get pregnant (willingly or not), they are usually the subject of research in reproductive health. This is not the case in other areas of medical research, where women have been notably absent from trials of drugs, for instance, mainly to avoid possible effects on the fetus of women who are pregnant. This has meant, however, that little is known about the possible differences in the effects of drugs (and different dosages) on women as opposed to men. However, because of their greater illiteracy and lack of decision making power (refer to the Gender Module, Session 3), women are frequently in a more vulnerable position than men, particularly in matters related to sexuality and reproduction.

Gender considerations in reproductive health research

These are questions on gender that have been developed by WHO, specifically for use in reproductive health research.

The topic of the research (1): Does the research address a demonstrated public health need and a need expressed by women or men?
Women and men have different reproductive health needs, which are both biologically determined and affected by gender roles. Reproductive ill-health affects women more than men, yet women are less likely to be in a position to have their voices heard concerning their own priorities in health needs. The research proposal should provide evidence that the proposed research responds to women's (or, as appropriate, men's) expressed or felt needs in reproductive health.

The topic of the research (2): Is the research likely to contribute to reducing gender inequities in health and health care?
The principle of gender equity means that the proposed technology or intervention should reduce disparities in health between men and women, and not make them worse. The principle of equity means that those with the greatest need have the greatest claim on resources. The proposal should describe how the proposed research will affect gender equity, and at least demonstrate that it will not increase inequities or inequalities between women and men. It should also discuss the potential constraints on adopting the technology, intervention or behaviour.

The process of research (1): Disseminating results and sharing knowledge
In reproductive health research, where the subjects may often be women, particular plans may need to be developed for ensuring that

the results of the research reach those subjects and the wide community of women. The proposal should present plans for sharing the information produced.

The process of research (2): Sex composition of the research team
Does the nature or topic of the research make it important that the researchers are women rather than men, or vice versa?

Handout

1 Ethical and appropriate research

Note: This case is fictitious, but is based on information from a variety of published sources.

A request for your comments

Your Ministry of Health has been approached by outside researchers to carry out a field trial of quinacrine, a new method of non-surgical female sterilization. The purpose of the study is to assess the acceptability and effectiveness of quinacrine as a non-surgical method of sterilization, among healthy women desiring no more children, in some population groups in your country. The Ministry asks you to give your comments on whether you think the research is appropriate and ethical, and provides you with the following information which has been given to them by the researchers.

The information the ministry gives you

Quinacrine

Quinacrine was developed in the 1920s and used as an anti-malarial drug during the Second World War. Subsequent infection-related uses were for tapeworm infestation, amoebiasis, and giardiasis. It is an effective sclerosing agent that causes inflammation that eventually leads to scar formation. As a method of non-surgical sterilization, it is introduced in pellet form (7 pellets of 26mg each, totalling 252mg) into the fundus of the uterus during the proliferative phase of the menstrual cycle, where it causes local inflammation resulting in tubal occlusion after 6–8 weeks. Introduction is done with an IUD inserter.

Quinacrine is safer than surgical sterilization: no case fatalities for 100 000 quinacrine sterilizations in comparison with the range for surgical sterilization of 2 per 100 000 in industrialized countries to 20 per 100 000 in some developing countries. Major complications are also lower for quinacrine sterilization, reported at a rate of 0.03 per cent compared to 1.7 per cent for laparoscopic sterilization.

In terms of long term complications, being a relatively new method these are not definitely known. Cancer is one concern, but it may take 10–20 years to appear. Oral administration of quinacrine at higher doses and over longer periods than those needed for quinacrine sterilization has not been associated with reports of increased cancer risk.

Background and rationale for the study

Current methods of female sterilization – tubal ligation or laparotomy – are quite invasive and costly in terms of both the training of medical personnel and the equipment needed for carrying out the procedure. The procedure is not 100

per cent effective, and can cause side effects. There is, therefore, a need for a safer method that would require less expertise and less of a technological investment than surgical sterilization. Quinacrine is one such method. Because it has been available on the market for many years for other medical uses, it is extremely cheap (less than $1 per dose of pellets needed for sterilization).

Quinacrine has already been used in over 100 000 women in different parts of the world. No serious complications have occurred and side effects have been moderate and transient. These results might suggest that the product could be introduced into any country without study, but since quinacrine has not up to now been studied in the African context, the investigators feel that it is necessary to study the effectiveness and acceptability of quinacrine specifically in African women. This would also provide an opportunity to accumulate additional data on the effectiveness and side effects of the product, and as a result to design appropriate training materials for health personnel and potential users.

The maternal mortality ratio in South Africa as a whole is 170 per 100 000 live births, but in some parts of the country it is much higher than this. The benefits of a new contraceptive that can raise contraceptive prevalence, and thereby lower maternal mortality, will be especially great in an area of high maternal mortality and low contraceptive prevalence.

The proposed study would recruit subjects from two rural areas and two poor urban areas in the country. The researchers feel that, because of the cheap price and the urgent need for preventing unwanted pregnancies, quinacrine would be a particularly useful method for low income women.

Additional notes given to you by your research assistant

2. It seems that there was a very big study (about 30 000 women) carried out in Vietnam, the results of which were published in *The Lancet* in 1996. However, there was subsequently a public debate about this because of criticism of the study from various quarters, including WHO. First, it seems that only a small sample of the women were followed up, so that there was concern about what had happened to the other women. Second, a WHO Toxicology Panel looked at the data on quinacrine and concluded that, since some animal studies showed that quinacrine might be carcinogenic (cancer-causing), additional toxicological studies were needed before clinical trials of the method in humans should proceed. It recommended formal toxicological studies on the possible carcinogenicity of quinacrine administered into the uterus.

3. Quinacrine has been approved for various medical purposes by the United States Federal Drug Administration, but not as a method of female sterilization through tubal occlusion. In fact approval has not been sought for such use in the United States. As far as we know, no national or international drug authority has given its approval.

4. Some international journals have published articles indicating a lack of good scientific evidence that quinacrine is safe for use as a female sterilizing agent. Attached are two such articles. (See the readings for this session.)

SESSION 4

Evidence for planning: reconciling evidence from different sources (Case: maternal health)

What participants should get out of the session

Participants will:

- recognize that research results reflect what question was asked, how the evidence was gathered, and from whom it was solicited
- understand the need to reconcile evidence from different sources for sound decision making
- be able to identify gender bias in the collection, analysis, interpretation and presentation of health information.

2 hrs 20 mins

2 hours and 20 minutes

Prior preparation

- Participants have to be assigned readings on the day before this session is run, as explained in Activity 1, p.256. They will read their articles individually in the evening, in preparation for the session.

Materials

- Handout: "Instructions for group work on maternal health"
- flip chart: "Conclusions from readings on maternal health", based on table on p.257
- blank overheads

Readings for the participants

1. Jejeebhoy SJ. Safe motherhood: empower women, ensure choices. Paper presented to the 10th Anniversary of Safe Motherhood in Sri Lanka 1997. Concluding section (unpublished document). Available online at: www.who.int/archives/ whday/en/pages1998/whd98_03.html

2. Rooney C. *Antenatal care and maternal health: how effective is it?.* Geneva, World Health Organization, 1992.

3. Spies CA et al. Maternal deaths in Bloemfontein, South Africa 1986–1992. *South African Medical Journal* 1995, **85:**753–755.

4. Women's Health Project. *Provision of maternal and neonatal services for the PWV province.* Johannesburg, Women's Health Project, 1994, Introduction and Chapter 4.

How to run the session

There are three activities. The first is an individual activity in which participants read a research report on maternal health in an evening, out of class hours. The second is a group activity where participants discuss the main findings of the article and prepare a group report identifying recommendations for an intervention based on the evidence they have. The third activity is a report-back from the groups followed by a discussion in the whole group.

Activity 1: A specific health problem

This activity has to be introduced to participants on the day before you do Session 4. Schedule about 10 minutes for this. Divide the class into four groups. Give each group one of the four readings listed above, which all look at how to improve on a particular health problem: maternal health. The different readings refer to different types of studies on maternal health, different data sources used, and how this leads to different recommendations. You may select readings addressing any other reproductive health problem from different angles.

40 mins

Activity 2: Recommendations

Explain the objectives of this session. Then ask participants to gather into their four groups. Each group has two tasks.

The first is to examine the report or article they have read and identify how gender has been addressed in the collection, analysis, interpretation and presentation of information.

The second task is for each group to consolidate their responses on the main findings of the article or report and come up with recommendations for action by health service planners to improve maternal health.

Distribute the handout "Instructions for group work on maternal health".

Groups will have about 30 minutes to complete their tasks and come back to the big group. Emphasize that the groups have to come up with recommendations for interventions. They should base their recommendations on what they have read, but not just reproduce the authors' recommendations.

1 hr 40 mins

Activity 3: Reporting back and reaching conclusions

1 hr

Step 1: Report-backs Call the groups into the big group and allow each group 10 minutes to present their reports. Encourage the listeners to question the justification for the recommendations. Allow five minutes per group for questions and answers.

Step 2: Writing up conclusions As groups make their presentations, write the main conclusions emerging from the reports in a table on a flip chart. The following table is an illustration.

Example of conclusions from readings on maternal health

Article or report	Discipline	Data source	Findings	Gender addressed?	Recommendations
Antenatal care and maternal health	Epidemiology	Published and unpublished studies	Effectiveness of antenatal care in preventing maternal mortality is questionable, especially in developing countries	No	Need more research, both epidemiological and operational, which identifies interventions that are known to be effective in developing country settings
Maternal deaths in Bloemfontein	Medicine	Case reports of 91 maternal deaths in a tertiary hospital	Maternal mortality ratio (MMR) for the institution was 171 per 100 000 live births. 71 per cent of the deaths were from direct obstetric causes. 35 per cent of deaths could have been prevented	No	Improve obstetric care in, and institute early referrals from, hospitals which refer complications
Safe motherhood	Social sciences	Published and unpublished reports and studies	Empowerment of women is an important factor in realizing safe motherhood	Yes, in the analysis, interpretation and presentation of information reviewed	Empowerment of women and expansion of women's choices should form a core element of safe motherhood interventions
Provision of maternal and neonatal services	Social sciences	Discussions with women who had used delivery services	Women reported negative experiences of maternal/neonatal health services	Yes, in framing research questions and in the interpretation of results	Develop interventions and make changes to meet women's needs

20 mins

Step 3: Discussing a gender perspective in research

Point out that the inclusion of women as study subjects (for a health concern that affects only females) does not in itself make for a gender perspective in research. A gender perspective calls for the systematic consideration of relevant gender issues in framing research questions, in data collection and in the analysis and interpretation of information.

Are there ways in which the studies on antenatal care and the hospital-based maternal mortality study could have addressed important gender issues? Sometimes, the study design and the sample population make this difficult. For example, if the maternal mortality study depended on hospital records, then unless these records are reworked to include gendered information, a gender analysis cannot be carried out.

20 mins

Step 4: Eliciting appropriate interventions

Challenge the group to come up with a package of interventions that would reconcile evidence from these various sources. Ask participants to summarize the main learning points from this session. Add to these as necessary.

Main points for closing this session

The research methods influence the recommendations

Different research methods allow us to reach different conclusions about what is needed to address a particular problem. This leads to different recommendations for interventions.

Different disciplines ask different questions

Health research includes a wide array of disciplines including demography, social sciences and epidemiology. The nature of questions asked is determined by the discipline of the researcher.

Use qualitative and quantitative information

It is often useful to include both qualitative and quantitative information when addressing a health problem.

A package of interventions

Data from different sources and disciplines often needs to be reconciled to come up with a package of interventions that will address the complex range of issues contributing to a health problem.

Be careful about generalizing

Not all published data can be generalized to other situations.

How to address the lack of a gender perspective

There is often very limited evidence on the gender dimensions of a health problem. This usually leads to the omission of gender issues from interventions. It would be useful to adopt a two-pronged approach: advocating for more research on gender issues on the one hand, and ensuring that interventions consider explicitly their impact on females and males separately, on the other.

Health interventions are informed by more than just evidence

Available evidence is not the only factor to consider when making decisions about health interventions. Practical and political interests and questions of feasibility play an important role. (The Policy Module and the Health Systems Module will be addressing some of these factors.) Being familiar with the relevant evidence will help us assess the appropriateness of interventions that are being implemented and offers us scope for advocating for change.

Session developed by Sharon Fonn

Handout

1 Instructions for group work on maternal health

You have all read an article or a published report on maternal health. You and your group have two tasks:

The first is to identify how gender issues have been addressed in the collection, analysis, interpretation, and presentation of information. Ask yourself questions like: does the information on women's characteristics include data on women's status so that an analysis of status and delivery outcomes could be carried out? Is the information collected, analysed, interpreted and presented in a manner that provides hypotheses on the impact of the gender based division of labour, gender roles and norms, access to and control over resources, or power, on the health problem under consideration?

The second task is to consolidate the main findings of the article or report and come up with recommendations for action that should be taken by health service planners to improve maternal health. See the information in the report as the primary data on which you should base your planning decisions.

Prepare a 10 minute presentation based on your interpretation of the article or report, focusing on the following questions:

- What discipline(s) do the questions raised in the article/report represent?
- What data source(s) does the article/report use?
- What are the main findings?
- Is gender addressed? If yes, in what ways?
- Based on the above, what recommendations would you, as a group, make on interventions to improve maternal health?

Make an overhead presenting your findings in table form, like this:

Article or report	Discipline	Data source	Findings	Gender addressed?	Recommendations

SESSION 5

Evidence for policy and programmes: selecting appropriate technologies for fertility regulation

What participants should get out of the session

Participants will:

- develop skills for identifying the information needed for selecting technologies for fertility regulation that are appropriate to a given setting
- be able to integrate gender and rights concerns when making this selection.

2 hrs 45 mins

2 hours and 45 minutes

Materials

- Handout 1: "Instructions for group work on making policy recommendations"
- Handout 2: "South Africa"
- Handout 3: "Nepal"
- Handout 4: Specifications of existing methods of fertility regulation (to be prepared by the facilitator). One possible source for this is www.rho.org

- overhead: "The user/technology/service interface", on p.263
- overhead: "Some examples of demand factors", on p.264
- overhead: "Some examples of supply factors", on p.264
- overhead: "Summary of what we know about users' perspectives on fertility regulation technologies", on p.265

Readings for the facilitator

1. Cottingham J. Beyond acceptability: users' perspectives on contraception. In: Ravindran TKS, Berer M, Cottingham J, eds. *Beyond acceptability: users' perspectives on contraception.* London, Reproductive Health Matters, 1997: 1-4.

2. Snow RC. Each to her own. In: Sen G, Snow RC, eds. *Power and decision: social control of reproduction.* Boston, Harvard School of Public Health, 1994.

3. World Health Organization. *Contraceptive introduction reconsidered: a review and framework.* Geneva, WHO, 1994.

Reading for the participants

Reading 3.

How to run the session

There are three activities. The first is your opening lecture which provides a framework for selecting appropriate fertility regulation technologies. Participants then break into small groups to do a document review of national data from two countries and prepare recommendations for the technologies to be selected for these settings. The groups report back and the session closes with a discussion.

45 mins

Activity 1: Your input

10 mins

Step 1: Sharing personal experiences

Ask volunteers to share their personal experiences of fertility regulation. What were the factors that influenced their choice of contraceptive method?

The responses usually include factors such as:

- postponing child-bearing or not wanting to have more children
- the effectiveness of the method
- the side effects of the method
- whether the method interferes with sexual activity
- whether the method is easy to use
- the need for secrecy
- access to health services
- whether the method is provider-dependent
- the range of methods readily available in the public health system
- the availability of abortion, in case of method failure.

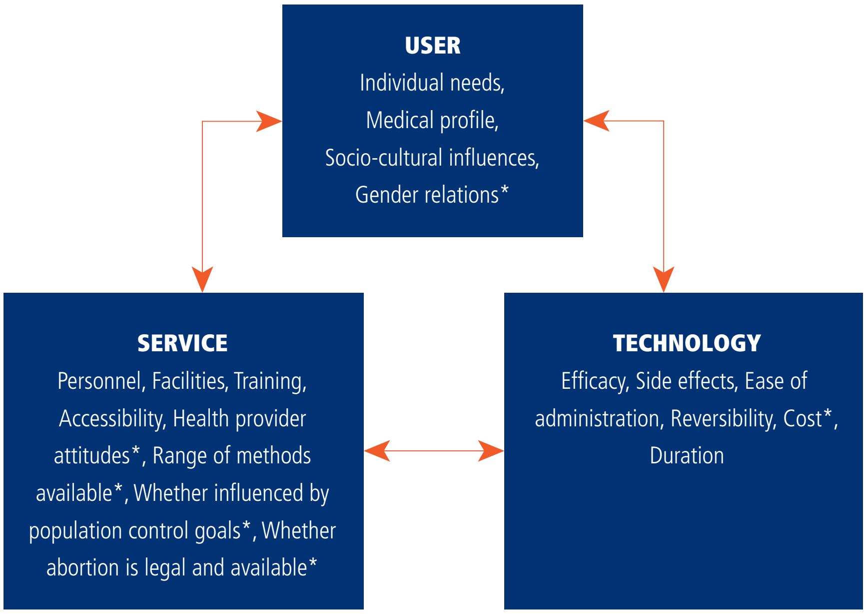
Group the factors into three main categories: those that are related to the characteristics of the user, those that are related to the characteristics of the technology, and those that are related to health services.

10 mins

Step 2: Framework for selecting appropriate fertility regulation technologies

Put up as an **overhead** this framework for selecting appropriate fertility regulation technologies. Go over factors relating to each dimension of the interface which need to be considered when selecting fertility regulation technologies that are appropriate for a given setting.

The sorts of ideas that might come out of each group



* Not part of the original framework
Source: Spicehandler J. *Contraceptive introduction reconsidered: a review and framework.* Geneva, World Health Organization, 1994.

Highlight the factors related to service delivery in particular, because these do not often come up in the earlier discussion on factors determining individuals' choices of technologies. Apart from considerations related to the health system's capability in relation to infrastructure and there being trained personnel to administer the technologies without compromising on quality, there are a number of other factors that need to be considered.

For example, countries which have had population control programmes driven by demographic targets have geared services to provide methods which are most effective in fertility reduction, but there is often no scope for individuals to select a method of their choice and which is appropriate for their reproductive goals. (Refer back to Session 4 in the Rights Module which discusses the violation of rights this represents.) Health provider attitudes in many such settings have been shaped by policy directives to maximize the number of acceptors of contraception, and not by quality considerations.

The availability or otherwise of legal abortions in the public health services is another factor that would influence whether or not barrier methods – which are not the most effective in preventing pregnancy – are a good option. The disadvantages of these have to be balanced against their advantages for preventing STIs/HIV.

The extent of STIs including HIV must, nonetheless, be seriously considered when selecting optimal contraceptive technologies for a given setting. Barrier methods such as the condom are the only means of prevention at this stage, and condoms warrant inclusion in any setting where such infections are a serious threat.

In countries where family planning has been integrated with the maternal and child health (MCH) programme, men have been excluded from service delivery, as have adolescent girls, and, in many instances, women who are not currently married.

Draw attention to the ways in which women's rights and degree of autonomy impact on their contraceptive options, and the need to take these into account in any planning process for fertility regulation programmes. Some examples, such as the need for secrecy, have been highlighted in Step 1.

15 mins

Step 3: Demand and supply factors influencing contraceptive behaviour

Factors influencing contraceptive behaviour in different settings are also classified according to demand factors and supply factors. Put up **overheads** of these two boxes.

Some examples of demand factors

- age profile of the population and prevailing norms for age at marriage, age at first birth, and the birth interval
- demand for delaying, spacing or terminating methods among different age groups
- abortion rates (if available) and the distribution of abortions by age
- regional health conditions, including anaemia and hypertension, and particularly the age specific incidence (prevalence) of STIs and HIV, and the need to reconcile fertility regulation with disease prevention
- gender relations, for example: do fertility decision-making roles within the home require women to use contraceptives secretly? Do sexual roles preclude use of barrier methods within marriage? Is male sterilization socially feasible?
- preferences of local users (and potential users) for different contraceptive attributes: extent and length of effectiveness, non-reversibility, resistance to chemical or mechanical methods, and whether use is associated with each act of intercourse (as in the case of barrier methods)
- tolerance for bleeding disturbances
- social acceptance of abortion.

Some examples of supply factors

- prevailing distribution options
- nature and quality of the distribution options
- provider capabilities
- opportunity for follow-up
- initial and recurrent costs
- availability and quality of abortion services.

10 mins

Step 4: Users' perspectives

Overhead What do we know about users' perspectives on fertility regulation technologies?

Summary of what we know about users' perspectives on fertility regulation technologies

Contraceptive users lack complete information about methods and services.

Women's and men's needs and preferences change over time and vary with the person's stage of life.

Users like safe and effective methods; side effects and method failure are the major reasons why women discontinue and do not use contraception.

Individual perspectives and preferences vary widely and defy generalization.

There is a limited range of methods available in many developing countries.

There is a lack of information about: the perspectives of men, adolescents, women having an abortion, women having repeated abortions, women in the post-partum period.

Source: Cottingham J. Beyond acceptability: users' perspectives on contraception. In: Ravindran TKS, Berer M, Cottingham J, eds. *Beyond acceptability: users' perspectives on contraception*. London, Reproductive Health Matters, 1997:1-5.

It is clear that a mix of methods is needed, catering to the varied needs of different sections of the population and also for the same individual at different stages of her or his reproductive span.

1 hr

Activity 2: Choosing appropriate fertility regulation technologies

Divide participants into four groups. Two groups will review evidence from one particular country to make an assessment of the fertility regulation technologies most appropriate for that setting. They will have to present the evidence for making their choices, and identify other evidence they would need to ensure that these choices:

- are feasible and realistic
- take into account users' perspectives and their rights
- contribute to gender equality or, at least, do not run counter to it.

The examples provided are from South Africa and Nepal (Handouts 2 and 3). Handout 1 sets out the instructions for group work and reporting. You will have prepared Handout 4, listing the characteristics of different methods of fertility regulation, to help participants make their decisions about the most appropriate methods for the country settings.

Participants have about one hour to read the handouts, decide on the fertility regulation methods they would recommend, identify additional evidence needed, and prepare a five minute presentation.

1 hr

Activity 3: Reporting back on chosen technologies

40 mins

Step 1: Report-backs

Each group has 10 minutes for a report-back and discussion. As each group reports, note down the justifications they give for their choice of technologies and the evidence they mention.

Challenge and probe

For example, groups often mention male condoms as a method of choice. They justify this by saying it is the most appropriate method for prevention of STIs/HIV and a male method. Challenge them to think about the kind of evidence they would need for deciding that condom promotion is feasible. Have they looked at current levels of condom use? What other information would they need (costs, existence of community-based distribution or other social marketing programmes, male attitudes to condom use, women's perspectives on condom use, and so on).

There may be population groups whose needs may not have been addressed, for example adolescent girls. Would they suggest introducing a new method? If yes, which one? What further information will they look for to ascertain that this would be appropriate?

20 mins

Step 2: Group discussion

After all four groups have reported back, move on to a general discussion on the kinds of evidence needed on users, services and technology to be able to choose appropriate methods of fertility regulation. Refer back to the framework on the interface, and start a list of indicators/information under each dimension.

Examples of the kind of information needed on user profile and user preferences:

- contraceptive prevalence by methods available
- proportion of women with an unmet need for contraception
- proportion of users of male condoms and male sterilization among users
- distribution of women with an unmet need by reasons for not using contraception
- age specific fertility rate in the 15–19 age group
- rates of HIV incidence (male and female)
- STI prevalence rates

- user perspective studies indicating method preferences, perceptions about quality of services, barriers to use
- indicators of gender differentials in access to education, employment and power.

Examples of information about services

- population policy of the country
- whether family planning services are state sponsored; whether they are provided alone, integrated with maternal and child health services, or integrated with primary health care
- range of methods available and cost of these
- legal status of abortion
- information on health services, such as per capita public expenditure on health, percentage of population with access to primary health care services, doctor-population ratio
- indicators of women's access to health care, such as proportion of deliveries that take place in health facilities, proportion of pregnant women using antenatal services
- studies on quality of care in family planning services and in health services in general.

Examples of information about the technologies

- side effects and contra-indications
- availability
- cost
- ease of administration
- potential for abuse
- common concerns and complaints that users have about the method.

Main points for closing this session

Matching technologies to local needs and service capabilities

Matching technologies to local users' needs and service capabilities should be a logical step in the delivery of all technologies. In many aspects of health care, this is the case. But the selection of the "optimal" mix of technologies for fertility regulation has unfortunately not included such considerations in many settings.

Getting the mix right

Personal needs for fertility regulation technology vary considerably, and existing technologies offer a range of different features. Hence, we emphasize an appropriate balance or mix of fertility regulation methods.

Upholding gender equality and rights

Selecting appropriate fertility regulation technologies can be done in a way which upholds gender equality and rights, and features quality of care (as one of these rights). This requires attention to the nature of the service setting, the profile and preferences of users, and the characteristics of the technologies under consideration.

Delivery of family planning

The selection of an appropriate mix of fertility regulation technologies is a necessary but not sufficient condition to ensure that these are available to users in a way that upholds gender equality and rights. The latter requires fundamental changes in the delivery of family planning services – from a population control to a rights perspective (as detailed in Session 4 of the Rights Module).

The evidence we need is there

Much of the evidence needed for making an appropriate selection of fertility regulation technologies already exists, and has to be identified and applied suitably.

Session developed by Rachel Snow, TK Sundari Ravindran and Khin San Tint

Handout

1 Instructions for group work on making policy recommendations

The information you will be given

You will be given a case example with health and population data for an existing country (Handout 2 or 3). You will also be given Handout 4 with current data on the characteristics of different methods of fertility regulation.

Make a policy recommendation about fertility regulation technologies

Referring to the framework presented earlier in the session (users, services, technologies), and making use of the information provided in the handouts, you have one hour within which to review the evidence and make a recommendation to the ministry about which three fertility regulation technologies would be most appropriate for the national programme. A wider range of methods would certainly be desirable for most programmes. However, priorities for selected methods are commonly made within national and other (such as NGO) programmes, and we ask you to do the same. Prioritize the three technologies that you feel would provide the safest, most acceptable, and most beneficial options for this national programme.

Justify your choices

Explicitly address the following points in your summary presentation.

How do you explain or justify your selection, with regard to the available information on:

- users' perspectives and their rights?
- underlying health needs and risks?
- the quality of existing services – can the method be delivered with assurance of quality?
- the rights and empowerment of women – will the method contribute to gender justice, or at least not run counter to it?

Prepare a six to eight minute presentation. Present your findings in a table like this:

	Fertility regulation technology assessed as appropriate (top 3 choices)	Key evidence on which selection has been based	Additional evidence (indicators, types of information) that would have been most helpful to our decision-making
1.			
2.			
3.			

Handout

2 South Africa

South Africa's population was approximately 40 million in 1999. The population growth rate was 1.8 per cent. Life expectancy at birth in South Africa is now 47.3 years for males and 49.7 years for females. *[1]* This low life expectancy is a direct consequence of the HIV/AIDS epidemic, with more than 1.3 million believed to be infected with the human immuno deficiency virus (HIV) in the late 1990s. Surveys show that HIV infection is more common among women than men, and that young women between the ages of 15 and 24 years are disproportionately affected. *[2]*

The total fertility rate (TFR) in South Africa, according to the Demographic and Health Survey (DHS) of 1998, was 2.9 for the period 1995–1998. Differentials in fertility rates are wide, with a TFR among non-urban women (3.9) almost double that among urban women (2.3). Further, the total fertility rate is 3.1 among Africans, 2.5 among coloureds and 1.9 among whites. Fertility rates are also higher in the Northern Cape, Eastern Cape and KwaZulu-Natal provinces, and lowest in the Free State, Gauteng and the Western Cape provinces. *[3]*

Information on fertility rates by age group is not available from the DHS. However, a recent study states that adolescent childbearing levels are high, with more than 30 per cent of 19-year-old girls reported to have given birth at least once. *[4]*

Three quarters of all women covered by the DHS of 1998 had never used a method of contraception, and 50 per cent were currently using contraception. Of women who were currently married or living with a man, 56.3 per cent were current users of contraception. Among women who were sexually active during the four weeks preceding the survey, 62.4 per cent were current users of contraception. *[3]*

Current use of contraception by methods, South Africa *[3]*

Percentage of all women, currently married women and sexually active women currently using contraceptive methods, South Africa 1998 (age 15-49 yrs)

Contraceptive method	Percent currently using, among		
	All women (15-49 yrs)	Women currently married or living with a man (15-49 yrs)	Sexually active women (15-49 yrs)
Any method	50.1	56.3	62.1
Any modern method	49.3	55.1	61.2
Pill	9.3	10.6	13.2
IUD	1.2	1.8	1.9

chart continues

Contraceptive method	Percent currently using, among		
	All women (15-49 yrs)	Women currently married or living with a man (15-49 yrs)	Sexually active women (15-49 yrs)
Injection	27.3	23.2	30.1
Diaphragm/foam/ jelly	0.0	0.0	0.0
Condom	1.9	1.7	2.3
Female sterilization	8.7	15.8	12.0
Male sterilization	0.9	2.1	1.7
Any traditional method	0.6	0.9	0.7
Number of women	11 735	5 077	6 062

A recent study (1992–97) in the Agincourt sub-district of Bushbuckridge, a rural region of the Northern Province adjacent to South Africa's border with Mozambique, found that the proportion of women who used contraceptives before giving birth was relatively low among adolescents and young women (4 per cent at ages 12–16 and 10 per cent at ages 17–21), and was somewhat higher among older women (20 per cent at ages 22–29 and 18 per cent at ages 30–49). This pattern is reversed after childbearing in the youngest age groups, however, with 39 per cent of both the 12–16-year-olds and the 17–21-year-olds using contraceptives. *[5]*

The authors argue that South Africa's family planning policy, which targets married women and women who have been pregnant at least once, fails to address the contraceptive needs of young women, especially adolescents, before their first pregnancy. Better access to contraception will require, first, a recognition of the special needs of adolescent girls, including the skills necessary to negotiate with male partners. Second, it will require providing them with appropriate information on reproductive health, including contraception. It will also require an appropriate range of contraceptive supplies and services, and training of clinic staff. *[5]*

Contraceptive services in South Africa are available through the primary health care network. Abortion is legal, although services are still not readily available in rural areas because of infrastructural constraints and limited numbers of trained personnel. There are no recent studies on the quality of care in family planning services. However, according to a study conducted in 1992–93, women receiving services in the public as well as the private sector experienced long waiting periods, limited information and choice of methods, sometimes inadequate technical competence, and they were not asked what they needed or how they felt. In addition to improvements in these respects, the women suggested better education about health, contraception and sexuality in schools and communities, and specific changes in the training of health care workers. *[6]*

Total health expenditure as a percentage of the country's gross domestic product (GDP) is 7.1 per cent, and public expenditure constitutes 46.5 per cent of health expenditure. Public expenditure per capita on health was 184 international dollars (internationally comparable, not dependent on local exchange rates) in 1999. *[1]*

The government of South Africa has pledged its commitment to the improvement of health services by including the right to health in the new Constitution, and identifies reproductive health as a priority. However, it has to contend with the public health legacy of apartheid, including wide variations in the distribution, coverage and quality of health services across provinces and between urban and non-urban areas.

References

1. **World Health Organization. *World health report 2000.* Geneva, WHO, 2000.**
2. **http://www.pathfind.org/worldwide/safrica_2htm (Date accessed: October 2000).**
3. **South Africa Department of Health. *South Africa demographic and health survey 1998.* Preliminary report. Pretoria and Calverton, Medical Research Council and Department of Health, and Macro International Inc., 1999.**
4. **Kaufman CE, de Wet T, Stadler J. *Adolescent pregnancy and parenthood in South Africa.* Policy Research Division Working Paper No. 136. New York, The Population Council, 2000.**
5. **Garenne M, Tollman S, Kahn K. Premarital fertility in rural South Africa: a challenge to existing population policy. *Studies in Family Planning,* 2000, 31(1):47–54.**
6. **Gready M et al. South African women's experiences of contraception and contraceptive services. In: Ravindran TKS, Berer M and Cottingham J, eds. *Beyond acceptability: users' perspectives on contraception,* London, Reproductive Health Matters, 1997.**

Handout

3 Nepal

Nepal had a population of about 23.4 million in 1999, with an annual population growth rate of 2.5 per cent. Life expectancy at birth was 57.3 years for males and 57.8 years for females. *[1]* The under five mortality rate for the country is high, at 139.2 per 1000 live births in 1996. The maternal mortality ratio per 100 000 live births was estimated to be 539 (1996). The female literacy rate in 1996 was 37.8 per cent compared to 67.9 per cent for males. While the female work participation rate was 40.4 per cent (1991), women constituted only 15.4 per cent of all workers in the organized sector. Less than 5 per cent of parliamentary seats were held by women in 1997, and only 2 per cent of ministerial seats. *[2]*

Nepal's total fertility rate (TFR) was 4.6, according to the Nepal Family Health Survey (NFHS) of 1996. *[3]* Adolescent fertility rates are high. NFHS figures show that more than half the women aged 19 years have had at least one birth or were currently pregnant. However, most of these are not premarital pregnancies, as 43 per cent of women in the 15–19 age group are married.

The available data on HIV suggest that the epidemic is still in an early phase, but the cumulative number of self-reported cases of HIV and AIDS has increased from 467 in 1996 to 1778 cases in November 2000. *[4]* While HIV infection rates remain low in the general population, recent studies among commercial sex workers (CSWs) and intra-venous drug users (IVDUs) suggest that Nepal has reached the stage of a concentrated epidemic, in which the HIV/AIDs prevalence exceeds 5 per cent in one or more sub-groups. Infection rates in female CSWs underscore their vulnerability, with evidence that the epidemic is more advanced in Kathmandu than elsewhere. Recent rates among CSWs in Pokhara were 1 per cent, *[4]* but prevalence has reached 17 per cent among CSWs in Kathmandu. *[4]* Risk appears particularly high among CSWs returning from sex work outside Nepal, especially from India.

While HIV surveillance data from intravenous drug users (IVDUs) showed persistently low rates of infection (1.6 per cent) through the early 1990s (1991–93), data from 1999 indicate that the prevalence has reached 40.4 per cent among male IVDUs. *[4]*

On the subject of STIs in Nepal, data from family planning attendees in 1999 found trichomonas vaginalis was 6 per cent, chlamydia 1.7 per cent, gonorrhoea 1.7 per cent and active syphilis 1 per cent. As expected, rates are higher among clients reporting symptoms to STI care facilities: Among male patients attending dermato-venerealogy (DV) services in 1997, the prevalence of chlamydia was 5.5 per cent, gonorrhoea 13.6 per cent, and active syphilis 9.5 per cent. Among female symptomatic patients, the prevalence of trichomonas vaginalis was 9.3 per cent, chlamydia 5.2 per cent, gonorrhoea 1.9 per cent and active syphilis 7.9 per cent. *[4]*

Current use of contraception by methods, Nepal 1996 *[3]*

Contraceptive method	Method mix among users of modern methods
Any modern method	100.0
Pill	5.4
IUD	1.2
Injection	17.3
Condom	7.3
Implants	1.5
Female sterilization	46.5
Male sterilization	20.8

Contraceptive services are available through public health facilities as part of the government's family planning programme. The government pursues a population policy committed to fertility reduction. Abortion is illegal and a criminal offence.

The country has a poor network of modern medical facilities, including public health facilities. Total health expenditure forms only 3.7 per cent of the gross domestic product (GDP), and public expenditure as part of total health expenditure is a mere 26 per cent, indicating that health services are paid for out-of-pocket by the population. Public health expenditure per capita in international dollars is 11 dollars. *[1]* Just over a quarter (27.6 per cent) of pregnant women are covered by antenatal services and only 7.6 per cent of the deliveries take place in institutions. *[3]*

References

1. World Health Organization. *World health report 2000*. Geneva, WHO, 2000.
2. World Health Organization. *Women of South-East Asia. A health profile.* New Delhi, WHO South-East Asia Regional Office, 2000.
3. Pradhan A et al. *Nepal family health survey 1996.* Kathmandu and Calverton, Ministry of Health, New ERA and Macro International Inc., 1997.
4. University of Heidelberg/National Centre for AIDS and STD-HIV Control Project. *Briefing report 2000.* Kathmandu, Nepal. UoH/NCASC STD-HIV Control Project, 2000.

SESSION 6 Evidence for monitoring: reproductive health indicators

What participants should get out of the session

Participants will:

- be familiar with the concept of different types of health indicators and their uses
- be able to come up with the indicators most relevant to specific settings
- have the skills to use and/or develop indicators that capture the gender and rights dimensions of a health issue or problem.

2 hrs 15 mins

2 hours and 15 minutes

Materials

- Handout 1: "Adolescent reproductive health project"
- Handout 2: "Safe motherhood project"
- Handout 3: "Improving the quality of family planning services"
- Handout 4: "Prevention and control of RTIs/STDs"
- Handout 5: "The gender/rights dimension"

- overhead: "Areas for impact assessment", on p.277
- 15 strips of paper each with an indicator from the box: "Global/national reproductive health indicators", on p.278
- flip chart marked as indicated on p.279
- overhead: "Critiquing and developing gender and rights sensitive indicators", on p.283

Readings for the facilitator

1. World Health Organization. *Indicators to monitor maternal health goals: report of a technical working group, Geneva, 8–12 November 1993.* Geneva, WHO, 1997.

2. World Health Organization. *Monitoring reproductive health: selecting a short list of national and global indicators.* Geneva, WHO, 1997.

3. World Health Organization. *Selecting reproductive health indicators: a guide for district managers.* Geneva, WHO, 1997.

Readings for the participants

Reading 3.

How to run the session

There are three activities. The first starts with a brief input introducing the concept of indicators. The second is a quiz on definitions of some commonly used reproductive health indicators included in WHO's global indicators list. The third activity consists of two options for small group work, followed by a group discussion. The first option will help participants construct and apply gendered reproductive health indicators for specific well defined local projects. The second option is for participants who are familiar with indicators and their use and who would benefit from a more challenging exercise on critiquing and developing gender and rights sensitive indicators.

30 mins

Activity 1: Indicators and how to use them

5 mins

Step 1: What are indicators?

Start with a series of questions to participants, along the following lines:

- Can you tell me the name of a good movie that you saw recently? Why did you think it was good?
- Would you describe neighbourhood X (the name of a part of the city or town where this course is taking place) as high income or middle income?
- What are some indications that would prompt you to say, on seeing a person, that she or he is not looking very well?

What participants do in each of the above instances is come up with indicators of a good movie, a middle income neighbourhood or poor health. Thus, indicators may be defined as evidence used to make an assessment about a complex situation or event.

5 mins

Step 2: What is a health indicator?

Begin with defining what a health indicator is, and give some examples.

A health indicator is usually a numerical measure which provides information about a complex situation or event. When you want to know about a situation or event and cannot study each of the many factors that contribute to it, you use an indicator that best summarizes the situation. For example, to understand the general health status of infants in a country, the key indicators are infant mortality rates and the proportion of infants of low birth weight.

10 mins

Step 3: Rates and ratios

Get participants to tell you the difference between rates and ratios, and explain these concepts if necessary.

Rates

An indicator is a rate or proportion when the numerator is included in the population defined by the denominator (Last JM et al. *A dictionary of epidemiology.* New York, Oxford University Press, 1995). For example, the literacy rate in a population has literate persons in the numerator and total population in the denominator.

Ratios

An indicator is a ratio when it is an expression of a relationship between a numerator and a denominator where the two are usually two separate and distinct quantities (Last JM et al, *A dictionary of epidemiology*. New York, Oxford University Press, 1995). For example, the population sex ratio has as numerator the number of males in the population, and in the denominator the number of females in the population.

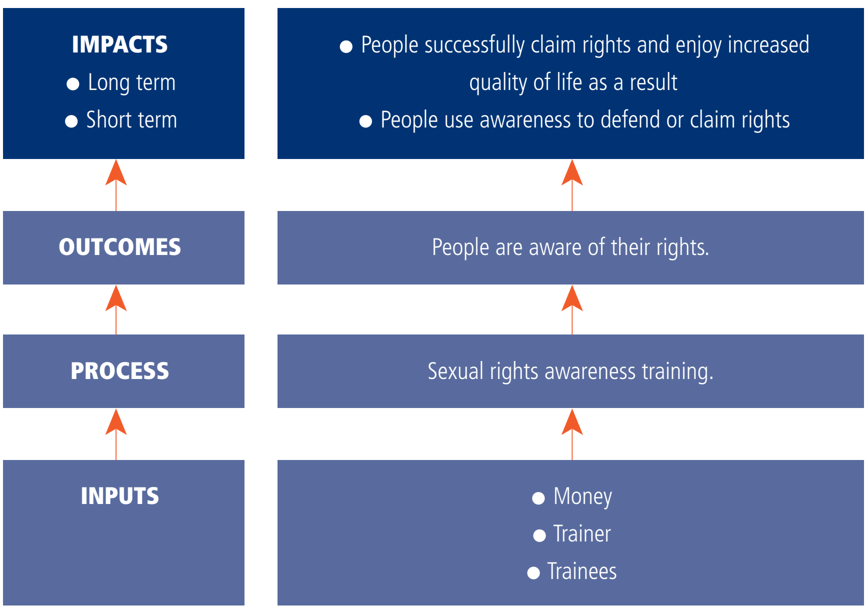
10 mins

Step 4: Multiple uses of indicators

Introduce participants to the multiple uses for reproductive (and other) health indicators. Put up the figure below as an **overhead.**

Indicators are used to measure inputs, process, and outcomes as well as the long term impact of a project. If the project is a sexual rights awareness training programme, the input indicators would be the amount of money, the numbers and quality of trainers, preparation time and so on. The indicators of process would be the number of training programmes conducted, the numbers of trainees covered. The outcome indicator would be the number of trainees who are aware of sexual rights. Impact indicators would be the proportion of trainees who use awareness to defend or claim rights, the proportion of trainees who have influenced the awareness levels of other members of society, and so on.

Areas for impact assessment



Source: Roche C. *Impact assessment for development agencies.* Oxford, Oxfam, 2000:2.

15 mins

Activity 2: Quiz: definitions of reproductive health indicators

Divide participants into two teams, team A and team B. Write each indicator from the WHO global/national reproductive health indicators (in the next box) on a strip of paper, fold it up and put all the folded strips into an open box. Have a quiz on the definitions of these indicators.

Global/national reproductive health indicators

a. Total fertility rate
b. Contraceptive prevalence rate
c. Maternal mortality ratio
d. Percentage of women attended at least once during pregnancy for reasons related to pregnancy
e. Percentage of births attended by trained health personnel (excluding trained and untrained traditional birth attendants)
f. Number of health centres per 500 000 population with functioning basic essential obstetric care (basic EOC)
g. Number of hospitals per 500 000 population with functioning comprehensive essential obstetric care (comprehensive EOC)
h. Peri-natal mortality rate
i. Percentage of live births of low birth weight
j. Positive syphilis serology prevalence in pregnant women attending for prenatal care
k. Percentage of women of reproductive age screened for haemoglobin levels who are anaemic
l. Percentage of obstetric and gynaecology admissions owing to abortions
m. Reported prevalence of women with genital mutilation
n. Percentage of sexually-active, non-contracepting women aged 15–49 years who report trying for a pregnancy for two years or more
o. Reported prevalence of urethral discharge in men aged 15-49 years.

Source: World Health Organization. *Monitoring reproductive health: selecting a short list of national and global indicators.* Geneva, WHO, 1997.

Put up a flip chart marked like this:

Indicator chosen	Definition	Rate/ratio	Marks: Team A	Marks: Team B
e.g. contraceptive prevalence rate	Number of women in the 15-49 age group using any modern method of contraception is the *numerator,* and the number of all women in the 15-49 age group is the *denominator*	rate		

Ask each team to take turns to choose a folded strip of paper and read out the indicator written on it. One member of the team comes to the flip chart and writes out the definition, stating what the numerator is, and what the denominator is.

For example, contraceptive prevalence rate will have to be written as:

$$\frac{\text{Number of women aged 15–49 currently using a method of contraception}}{\text{Total number of women aged 15–49}}$$

Push for precision in definitions – what would they define as a method of contraception? Modern methods? Traditional and modern? Which traditional methods? Are all women in the 15–49 age group included? Or is it only currently married women? And so on.
(A list of WHO definitions is available online at:
www.who.int/reproductive-health/pages_resources/
listing_global_monitoring.htm.

A complete and accurate response gets five marks. If both teams share in giving the complete definition, the marks are shared. The team with the highest marks is the winner.

1 hr 30 mins

Activity 3: Option 1: Gendered reproductive health indicators

30 mins

Step 1: Group work

Divide participants into four groups. Each group is given a hypothetical reproductive health project for which they have to develop indicators (Handouts 1, 2, 3 and 4).

1 hr

Step 2: Report-backs

One person from each group reports back to the whole group on:

- the reproductive health project under consideration
- indicators to be used and their definitions
- the attempt made to bring gender and rights dimensions into one or more of the indicators
- mode of collection of information on these indicators
- how often will the information be collected (for example, census information is collected once in a decade).

Each presentation should be five minutes and may be followed by a ten minute discussion.

Some of the indicators that may emerge from each of the groups are outlined below.

Adolescent reproductive health project

- proportion of female adolescents reporting condom use (this may be further refined, for example to specify regularity of condom use, access to condoms, or whether a condom was used in their most recent sexual encounter)
- 15–19-year-olds as a proportion of all abortion related obstetric and gynaecology admissions
- proportion of women in the 15–19 age group who have had one or more children or are currently pregnant.

Safe motherhood project

- percentage distribution of maternal deaths by place of death
- proportion of women who died at home or on their way to the hospital because the hospital was too far away
- percentage distribution of maternal deaths in hospital, by time between admission and death
- proportion of women reporting a delivery complication who delivered in a health facility.

Improving the quality of family planning services

- percentage distribution of all women using contraceptives, by method used
- proportion of women and men reporting that they were given adequate information on various contraceptive options available
- proportion of contraceptive users who are men
- proportion of contraceptive users reporting at least one follow-up contact with the health facility or health worker
- proportion of satisfied users at the end of x months following acceptance.

Prevention and control of RTIs/STDs

- proportion of clinic users who are aware of the symptoms of one or more RTIs/STDs
- number (and/or proportion) of clients seeking treatment for RTIs/STDs
- proportion of clients (by sex) whose partners have also sought treatment
- proportion of those diagnosed with an RTI/STD who completed treatment (reasons for not completing treatment: cost? access? quality?)
- proportion of those who completed treatment who are cured of the problem.

What to cover in the discussion following each presentation

Accuracy

Verify that the indicators are accurately defined, and that the numerator and the denominator of the indicator are specified wherever relevant.

Validity

Examine the indicators for validity, making sure that they measure what is supposed to be measured. For example, the proportion of women covered by antenatal care may be a measure of utilization, but not a measure of the success of a safe motherhood programme – unless it could be established that the kind of antenatal care provided helped to reduce the probability of maternal death or of serious morbidity.

Reliability

Examine the indicators for reliability, making sure they are not dependent on the subjective perceptions of the person collecting the data or the person reporting. For example, indicators such as "malnourished" are completely dependent on the perception of the data collector, unless the term is clearly defined as weight-for-age below xx, or body-mass-index (BMI) below yy, and so on.

Gender and rights

Which of the indicators addressed above had the potential to address the gender/rights dimensions of the issue? For example in the adolescent project, information on condom use should be collected from both girls and boys. In addition to finding out the proportion of girls aged 15–19 who are currently pregnant or have had a child, the proportion of boys aged 15–19 who have either fathered a child or are responsible for a current pregnancy could also be an indicator. This information may be collected by asking girls who are mothers or are currently pregnant about the age of the father. Antenatal records in health centres could routinely collect data on the age of the father.

In the safe motherhood project, a gender/rights dimension may be added to the indicator on the distribution of maternal deaths in hospital by time duration between admission and death, by asking for reasons for delay. Similarly, reasons for non-use of a health facility by women reporting a delivery complication would give insights into whether gender based discrimination, through the lack of access to resources and power, or through roles and norms, played a role in this delay.

To add a gender dimension to indicators for the family planning programme and the RTI/STD programme, indicators should be analysed by the sex of the respondent. In addition, finding out reasons for the non-use of any contraceptive method, or non-use of health services for RTIs/STDs from both women and men, could help bring out the role of gender in this.

Mode of data collection

Data on the indicators may be collected as part of routine data collected by health facilities, or routine records maintained by health workers. Alternatively, there may be a need for special surveys or studies. One criterion for choosing an indicator should be how easy it is to collect data on it. Thus, while in the adolescents' programme we could have come up with the indicator "proportion of adolescents having an unsafe abortion", data on this would be so difficult to collect that it is not helpful.

Timing of data collection

Draw participants' attention to the need for baseline information in order to monitor or evaluate any situation. For a three year project, data may be collected at two or three time points; and in routine data collection such as hospital records, data analysis may be carried out at two or three time points.

1 hr 30 mins

Activity 3: Option 2: Critiquing and developing the indicators

30 mins

Step 1: Groups review and discuss gender and rights sensitive indicators

Divide participants into four groups. Assign each group one element of quality of care (for example, accessibility) and give them a set of indicators to evaluate STD/HIV prevention services. (Make separate handouts for each group, based on the details outlined in the table "The elements of quality of care and their indicators" in Handout 5. Choose four elements of quality of care from this table for the groups to work on, making four different versions of Handout 5.)

Ask each group to review and discuss their indicators in relation to their gender/rights sensitivity: do they evaluate the responsiveness of services to gender/rights issues? If the group concludes that these perspectives are not adequately included in the indicators, then it has to rework the indicator. The group may also propose additional gender/rights sensitive indicators of the quality of care element under review.

30 mins

Step 2: Report-backs

Give each group seven minutes to make their presentation.

30 mins

Step 3: Group discussion

For the main points you need to draw out in this discussion, see Activity 3, Step 2 (accuracy, validity, reliability etc.).

Prepare an **overhead** indicating:

Critiquing and developing gender and rights sensitive indicators

- the quality of care element which you worked on
- the list of proposed indicators for evaluating this element
- indicators among these that are (or have been) gendered
- indicators that incorporate a rights dimension.

Session developed by TK Sundari Ravindran, Khin San Tint and Centro de Estudios de Estado y Sociedad (CEDES), Argentina

Handout

1 Adolescent reproductive health project

Instructions for group work

Your group has 30 minutes to work on the following problem. Nominate a reporter who will report back to the whole group. Your small group discussion should come to a close five to ten minutes before the half-hour is up to allow time for the reporters to write up their presentations.

The project

A new project for the improvement of the reproductive health of adolescents is being initiated in your district. The project is planned for a three-year period.

The objectives are:

- to promote condom use
- to prevent unsafe abortions
- to promote postponement of childbearing.

What are the indicators you will use for evaluating this project? How will you make one or more of these address the gender/rights dimension?

How will you collect the information on these indicators? How often will you collect it?

Handout

2 Safe motherhood project

Instructions for group work

Your group has 30 minutes to work on the following problem. Nominate a reporter who will report back to the whole group. Your small group discussion should come to a close five to ten minutes before the half-hour is up to allow time for the reporters to write up their presentations.

The project

Concern has been raised about the number of maternal deaths reported in your area. A safe motherhood project aimed at reducing maternal deaths over the next three years is to be implemented very soon.

The specific objectives are:

- to prevent delay between the development of a serious complication in pregnancy and reaching a health facility providing emergency obstetric care
- to prevent delay within health facilities in initiating appropriate treatment.

What are the indicators you will use for monitoring this project? How will you make one or more of these address the gender/rights dimension?

How will you collect the information on this indicator? How often will you collect it?

Handout

3 Improving the quality of family planning services

Instructions for group work

Your group has 30 minutes to work on the following problem. Nominate a reporter who will report back to the whole group. Your small group discussion should come to a close five to ten minutes before the half-hour is up to allow time for the reporters to write up their presentations.

The project

In your province, more than 80 per cent of contraceptive users have adopted female sterilization. Your brief is to improve the quality of family planning services offered in the five primary health centres under your supervision over the next three years.

You design a project, which aims to:

- widen contraceptive choice for women
- promote male methods of contraception
- improve follow-up services
- improve client satisfaction.

What are the indicators you will use for monitoring this project? How will you make one or more of these address the gender/rights dimension?

How will you collect the information on these indicators? How often will you collect it?

Handout

4 Prevention and control of RTIs/STDs

Instructions for group work

Your group has 30 minutes to work on the following problem. Nominate a reporter who will report back to the whole group. Your small group discussion should come to a close five to ten minutes before the half-hour is up to allow time for the reporters to write up their presentations.

The project

A new RTI/STD prevention and control project is being implemented in your health facility.

The objectives of the project are to:

- improve awareness of the signs and symptoms of RTIs/STDs
- promote treatment seeking among those with symptoms of RTIs/STDs
- encourage partner notification and treatment.

What are the indicators you will use for monitoring this project? How will you make one or more of these address the gender/rights dimension?

How will you collect the information on these indicators? How often will you collect it?

Handout

5 Gender and rights sensitivity of quality of care indicators

Instructions for group work

Your group has 30 minutes to work on the following problem. Nominate a reporter who will report back to the whole group. Your small group discussion should come to a close five to ten minutes before the half-hour is up to allow time for the reporters to write up their presentations.

The problem

You have been given the details of one element of quality of care for clinic based RTI/STI services, and indicators corresponding to this element. Review and discuss these indicators in terms of their gender/rights sensitivity: do they evaluate the services' responsiveness to gender/rights issues? If you conclude that the indicator lacks adequate gender/rights sensitivity, then rework that indicator. You may also propose additional gender/rights sensitive indicators of the quality of care element under review.

The elements of quality of care and their indicators

Element	Definition of element	Indicators
Accessibility and availability	• All have access to sexuality education • Clinic hours available are convenient for client • Distance/means/cost of travel convenient and affordable • Preventive and simple curative services affordable according to client's ability to pay • Cost of condom not a deterrent to use • High risk groups, such as commercial sex workers (CSWs), receive access to services through peer group outreach or other methods	• Percentage of the population under age 15 who have had sexuality education • Percentage of clients (percentage potential/former clients) report hours are convenient • Percentage of clients (percentage potential/former clients) report service location convenient/affordable • Percentage of clients (percentage potential/former clients) report services affordable
Acceptability	• Prevention and STD services delivered at socially acceptable venue • Acceptable length of waiting time for initial and follow-up visits • Sex, ethnic group, age status of clinic provider appropriate for client/potential client • Confidentiality maintained • Condoms acceptable	• Percentage of target community who go to clinic for health problems • Percentage of clients (percentage potential/former clients) reporting level of privacy as acceptable • Percentage of clients (percentage potential/former clients) who report waiting time as acceptable • Percentage of clients (percentage potential/former clients) reporting comfort with clinic provider • Percentage of clients (percentage potential/former clients) reporting confidentiality as adequate
Technical competence	Clinic provider: • Can identify facts of HIV/STD transmission and prevention • Can assess the relationship of contraceptive methods with STD risks for each client • Can diagnose and treat common STDs	• Percentage of symptomatic patients adequately assessed, diagnosed and treated • Percentage of clinic providers maintain adequate records of services provided and store them in a secure location

chart continues

Element	Definition of element	Indicators
Technical competence *(continued)*	● Refers patients with STD symptoms that clinic provider is unable to diagnose or treat ● Uses aseptic technique ● Uses protective clothing and gloves ● Can conduct risk assessment without moral judgements using green, yellow, red light approach; green = encourage low risk to continue their current behaviour; yellow =caution; red =stop risky behaviour ● Can recognize all people at risk of exposure to HIV ● Can recognize different presenting symptoms of AIDS plus symptoms of recurring yeast infections in women ● Has record keeping systems established and maintained	
Client–provider Interaction	● Confidentiality ● Can counsel client/commercial sex worker (CSW) with respect ● Can conduct risk assessment without moral judgements ● Freedom from coercion	● Percentage of clients satisfied with provider confidentiality and provider attitude ● Percentage of providers satisfied with amount of time per client
Information/ Counselling for client	● Information materials available ● Counselling of HIV/STD transmission and prevention to all adolescents prior to becoming sexually active, nd all currently sexually active adults ● Topics covered include information that: - STDs/HIV can be asymptomatic - STDs/HIV can present with symptoms such as pelvic pain, genital lesions and vaginal discharge - most STDs can be treated - without treatment, STDs can cause infertility or other serious health consequences - risk can be reduced through abstinence, postponed sexual activity, mutual monogamy, condom use and negotiation ● Instructions for condom use ● Sufficient time for provider to counsel client ● High risk groups, such as CSWs, should receive intensive counselling and access to services through peer group outreach or other methods ● Information, education and communication campaign associate condoms with prevention of transmission of HIV/STDs to children	● Percentage of women with pelvic pain, genital lesions and vaginal discharge counselled on STDs/HIV ● Percentage of clients counselled on STDs/HIV; risk reduction; condom use and negotiation ● Percentage of partners notified ● Percentage instructed on condom use ● There is a checklist of information that the provider should cover, and corresponding education material ● Percentage of clients feel sufficient time spent with providers
Essential supplies, equipment and medication needed, plus norms and standards	● Table, speculum, gloves ● Electricity ● First line of drugs for STDs ● Sterilizer or autoclave ● Refrigerator at clinic (kerosene if no electricity) ● Condoms, spermicides, provision and/or referral for other contraceptives	● Storage guidelines posted

chart continues

Element	Definition of element	Indicators
Essential supplies, equipment and medication needed, plus norms and standards *(continued)*	• Consistent supply of drugs, supplies, and necessary equipment maintained • Medications and condoms stored properly • Proper disposal of bio-hazardous waste	• Percentage of STD services and HIV prevention counselling offered with family planning, maternal health services • Percentage of clients obtained contraceptives
Comprehensiveness of care, and links to other reproductive health services	• Integrate all STD/HIV prevention with family planning/maternal health or other services where feasible and efficient • Referral for other contraceptives or services • Communication/referral system developed and operational	• Percentage of partners contacted • Percentage of referrals documented • Percentage of partners notified • Functioning follow up system
Continuity of care and follow up	• Partner notification (only after assessment of risk of violence if women) • Direct referral of partners by infected individuals seen by provider • Regular clinic hours • If possible, regular provider schedule • System to follow up client who has not returned • Follow up lab treatments (e.g. syphilis) • Follow up lab tests	

Source: Pan American Health Organization. *Quality of care in women's reproductive health: a framework for Latin America and The Caribbean.* Washington, PAHO, 1994.

SESSION 7

Evidence for service evaluation: applied exercises

What participants should get out of the session

Participants will:

- be acquainted with a range of techniques for data/information collection for service evaluation
- have hands-on exposure to constructing tools for data/information collection
- learn how to integrate gender and rights dimensions in data/information collection for monitoring and/or evaluating services.

5 hrs

about 5 hours of class time, and an evening's work after class

Materials

- Handout 1: "Instructions for group assignments on tools for collecting data"
- Handout 2: "How to design a questionnaire"
- Handout 3: to be prepared by the facilitator using: Britten N. Qualitative interviews in medical research. *British Medical Journal,* 1995, 311:251–253
- Handout 4: to be prepared by the facilitator using: Kitzinger J. Introducing focus groups. *British Medical Journal,* 1995, 311:299–302

- overhead: "Various data collection techniques", on p.292

How to run the session

The session starts with your input, in which you review qualitative and quantitative techniques for data collection. This is followed by a small group exercise where participants work in the same groups as they did in Session 6. Participants develop and pilot data collection tools for assessing the outcomes of the same projects as in Session 6. In the third activity the groups report back, and this is followed by a detailed discussion and feedback from you.

30 mins

Activity 1: Input on data collecting techniques

Various data collection techniques

Qualitative

1. Observation
- Provides detailed descriptions of programme activities, processes and participants
- Highly dependent on the skill, training, and competence of the observer
- Needs concentration, patience, alertness, sensitivity and physical stamina.

2. In-depth interviews
- Involves asking open-ended questions, listening and recording the answers, following up with additional relevant questions
- Informal conversational interview, interview using a general guideline, and standardized open-ended interview
- Purpose: allows us to enter into and document another person's perspectives.

3. Focus groups
- Interview with a small group of people (6–8) on a specific topic
- Aimed at obtaining high quality data in a social context where people can consider their own views in the context of the views of others
- Fairly easy to asses the extent to which there is a consistent shared view of the programme among participants.

Quantitative

4. Review of records
- Relatively inexpensive
- Some constraints due to type of records, classification, missing data
- Overall picture on programme's performance: who are the clients, coverage, morbidity.

5. Check-lists
- Provide a comparison matrix of different facilities
- Quick reference on what was done and what was not done.

6. Questionnaires
- Follows a well defined structure to prevent own interpretation
- All questions are asked in the same way
- Could use a combination of open and close-ended questions
- Respondents must fit their experiences and feelings into the researcher's categories unless the questionnaire is open-ended
- May serve to obtain comparable information across settings.

3 hrs

Activity 2: Developing and piloting tools for data collection

Tell participants to get back into the same groups as for the activity to develop indicators in Session 6 to work on developing data collection tools for assessing the outcome of the same projects.

Sub-divide each of the four groups into two: one to develop a tool for collecting qualitative information, and another for collecting quantitative data.

Those developing tools for quantitative data should make sure that their tools provide information related to the indicators they developed in the earlier session.

Those developing tools for qualitative information should specify what aspects they will collect information on, using their tool. For example, in the adolescent reproductive health project one aspect could be male adolescents in the community with a positive attitude to condom use. Each group will develop their tools and test them with another group. Handout 1 gives details of the process. Handouts 2 and 3 are about questionnaire design and interview and design and Handout 4 explains how to design guidelines for focus group discussion.

Inform the participants that they have to make a 10 minute presentation on the data collection tool they have developed. They also have to submit it in written form, for grading.

The presentation and the written report should address the following questions:

1. What were the changes made to this tool after the piloting? Why?
2. How have you addressed gender, rights and ethical issues in this tool?

When this session was run in Yunnan, China, an operations research (OR) exercise was used as the application exercise. Earlier, the OR approach had been introduced as part of Session 2, the introduction to health research. For the application exercise (Session 7) results from an OR study carried out in Kunming, China were used. The study was an assessment of the Maternal and Child Health Poverty Alleviation Fund, a health financing project to help low income mothers.

Participants were divided into two groups. One group was given the qualitative information from the OR study, and the other was given the quantitative data. Each group had to examine the data/information given and answer the following questions:

From the data, can you suggest why it was generated? What are the study hypotheses? How could we utilize the data? What are some possible biases? How could one reduce the biases?

The groups exchanged their responses in a big group discussion. Facilitators then gave their input on the actual OR study, its objectives, hypotheses, the analysis and interpretation of results, and how the data/information was used. Participants then had an opportunity to critique the study as it had been done, based on what they had learnt in the various sessions of this module.

2 hrs

Activity 3: Presentations and feedback

The questionnaire designing assignment may be used for grading, to contribute to certification where appropriate. Whether or not the assignment is graded, this activity would consist of detailed feedback from the facilitator to participants on how their questionnaires and information collection tools may be improved.

Each group has 15 minutes for the presentation and any discussion following it. The tools should be presented as an overhead and presentations should cover the changes made, as well as the gender, rights and ethical issues that have been addressed.

As the groups make their presentations, evaluate the tool and note down points for your feedback.

Ask for the following details:

- Who are the respondents? (sample units)
- How will they be chosen? (sampling from the sample population)
- What are the reasons for the above?
- Where will the data collection take place? Why?

Take the following points into account when you evaluate the tools.

The data collection tool is constructed so that the questions:

- will elicit unique responses
- are relevant to the issues being addressed
- are not repetitive
- are in logical order
- are sensitive to and respectful of the respondent.

Other points to look out for in the evaluation are how gender, rights and ethical issues will be addressed both in the tool and in the way information will be collected using the tool: for example, ensuring that both women and men are included in the sample, that questions pertinent to both sexes are included where relevant, that privacy is respected, that there is informed consent, and so on.

Give the participants detailed feedback immediately after each presentation. If you have time, you can give groups an opportunity to revise their data collection tools and resubmit them for evaluation.

Session developed by Mariana Romero and Khin San Tint

Handout

1 Instructions for group application exercise on tools for collecting data

Preparation

You were given handouts in Session 6 for developing indicators to evaluate reproductive health programmes. You have also been given handouts on questionnaire design (Handout 2) and interview design (Handout 3). And we have reviewed qualitative and quantitative techniques to collect data. Handout 4 is for your general information, and does not relate specifically to this assignment.

The assignment

1. **Review what you have learnt about data collection techniques**
   Individually, you have one hour to review the new handouts on data collection techniques.

2. **Develop your tool**
   Then, spend one hour as a group to develop and write your tool for collecting information for assessing the outcome of the programmes in Session 6. If you are developing a tool for quantitative data, make sure that your tool provides information about the indicators you developed previously. If developing a tool for qualitative information, specify which aspects you will be collecting information on.

   When developing the tool, bear in mind that the questions should:

- elicit unique responses
- be relevant to the issues being addressed
- not be repetitive
- be in logical order
- be sensitive to and respectful of the respondent.

   Be clear about:

- who your respondents are
- how they will be chosen and why
- where the data collection will take place and why.

3. **Pilot your tool**
   Once you have written the tool it has to be piloted with a few members of another group. All participants should make themselves available for an hour to be interviewed as part of the piloting process.

4. Revise and finalize

After this, your group has 1 hour and 30 minutes to revise and finalize the tools, discuss their strengths and weaknesses, and rights, ethical and gender issues that have arisen in the process.

Prepare a 10 minute presentation, and a written report which includes:

- the final tool
- changes that were made after piloting, and why
- ethical issues that you have considered
- rights issues that you have considered
- gender issues that have been addressed by your tool.

This assignment will be graded. All the members of one group get the same mark.

Handout

2 How to design a questionnaire

Source: Extracted and adapted from: Botha JL, Yach D. *Manual of epidemiological research methods: a supplement to perspectives in community health.* Abridged version of the IB-ESSA workshop manual. Tygerberg, South African Medical Research Council, 1987:17–18.

Step 1: Only ask the necessary questions

Questions should be based on your study objectives – keep them within the scope of the study. Short-list the variables that you need. Use existing questionnaires as a guide only. Design your questions to suit your particular study.

A short, well conceived questionnaire elicits much better information than a long, rambling, one.

Step 2: Word the questions carefully

Questions can be open-ended and the respondent replies in whatever way she or he chooses. The alternative is to have closed-ended questions where predetermined possible answer categories are marked off and coded. This ensures quicker, more standardized data collection.

How should questions be asked?

- Find out from potential respondents what questions are meaningful to them and how to phrase the questions to make sure that they are understandable and acceptable.
- Questions should be simple, concise and specific. Make sure that there are no ambiguities.
- Decide whether and where open-ended or closed-ended questions are most appropriate.
- Ask one question at a time. Break up complex questions into simple ones. For example "Do you use a method of contraception? If not, why not?" should be broken up as follows: "Do you use a method of contraception? Yes/No. If no, what are your reasons? If yes, which of the following methods are you currently using?" and so on.
- Avoid questions which suggest to the respondent the answer that is expected (this is called a leading question). For example "Do you believe that IUDs have adverse health effects?"
- Take special care with wording questions and locating them within the sequence of questions when seeking personal or sensitive information.
- Closed question categories should be mutually exclusive and exhaustive: there should be no overlap of categories, and all possibilities should be covered. Always allow for an "other" category where the respondent can specify the answer.

Step 3: The lay-out of the questionnaire

- Order the questions meaningfully to ensure a smooth, logical flow. Non- threatening items should be put first so that the respondent feels at ease.
- Provide visual markers to make the form easy to complete – for the interviewer in interviews and the respondent in self-administered questionnaires. Examples of visual aids include putting related questions in boxes and using arrows, flow diagrams, geometric symbols, and so on.
- Ensure good spacing and printing for easy reading, and enough space for filling in the responses.

Step 4: Pilot the questionnaire

- Select respondents who are similar to the target population.
- Do trial runs of the questioning, leaving space for noting required changes.
- Assess logistical issues such as time taken, wording, common responses which suggest categories for closed questions, and common misinterpretations of the question.
- Make the necessary changes.