

### Problem Identification and Definition

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- This section of the proposal depends upon information from previous research and the literature
- It should therefore contain the literature review. Before writing this section, you should:
  - Search the literature thoroughly for information about the problem you are researching.
  - Establish whether or not others are currently engaged in similar or related research.
  - Classify key literature on the subject.
  - Identify critical areas for research (i.e., shortcomings of previous studies or areas where no research has been or is being done).

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### Identify the problem

- State why you think the problem requires study
- **Problem identification for analytic epidemiologic research must proceed from the following three conditions:**
  - Indicate the discrepancy between the real or observed situation (*what is*) and the ideal, desired, or theoretical situation (*what should be*).
  - Indicate the alternative solutions or explanations for the discrepancy.
  - Indicate which of the alternatives you believe is the most likely to be correct and why.
- For exploratory or descriptive research, only the first condition is required. Conditions 2 and 3 may or may not apply.

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**Problem Identification Statements**

Example 1

- **Infant Mortality (Analytic Study):** Infant mortality is higher in Village A than in neighbouring villages. *There should be no difference in infant mortality between these villages.* Possible explanations are that Village A has (a) lower nutrition levels, (b) lower levels of breast-feeding, (c) poorer sanitary conditions, (d) lower maternal literacy. Our knowledge of lifestyles in these villages leads us to believe that infant mortality is higher in Village A because sanitary conditions are poorer than those in surrounding villages.

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**Example 2**

- **Increase in Vasectomies (Analytic Study):** Thirty vasectomies were performed in region A over the past six months. This number constitutes an abnormal increase, since *the region usually averages two vasectomies a month.* This increase may be due to support for this procedure from local community leaders or it may be due to a new promotional campaign undertaken by family planning clinics in Region A. Our team believes the primary influence is the new promotional campaign.

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**Example 3**

- **Adolescent Fertility (Descriptive Study):** Fertility is higher among adolescents than among women 18 to 24 years of age in City X. Public health officials felt *the fertility rate for adolescents should be lower.* In response to this concern, we propose to study the factors associated with adolescent pregnancy in order to identify high-risk groups and to begin formulating hypotheses regarding interventions for further study.

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**Example 4**

- Country X has a shortage of trained health professionals to provide intrauterine devices (IUDs) to women in rural regions. Therefore, the government initiated a program in 1985 to provide two months of training in family planning to traditional midwives. A study will be conducted to determine IUD retention rates for village women who received IUDs from rural midwives and those who received IUDs from physicians or nurse-midwives in a clinic setting.

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**Define the problem**

- Summarize current research and list issues needing further study.

**Problem definition may include information on:**

- *Magnitude.* What is the incidence and prevalence of the problem?
- *Time frame.* When does it occur? Is it current?
- *Geographic area.* Where does the problem generally occur?
- *Population.* Does the problem affect certain groups of people?
- If so, what are their characteristics?
- *Why?* What are the probable reasons for the problem? Is there agreement or conflict over these reasons?
- *Solutions.* What solutions have already been tried?
- How successful have they been?
- What untried solutions might there be?
- *Unanswered questions.* What parts of the problem need further research?

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**Example 5**

- Trained health professionals are currently (time frame) in short supply (magnitude of the problem) in rural areas of Country X (geographic area). Consequently, women residing in rural areas (population) have not adopted effective methods of birth control. In many developing countries, and particularly in rural areas, where there are few trained health providers, auxiliary personnel serve as health care providers. Thus, since 2005, traditional midwives have been providing family planning services to rural women in Country X (solution).
- The traditional midwives are well accepted as paramedics in rural areas. Their traditional tasks of delivery and care of the mother and child permit them to easily provide family planning services to those mothers who wish them (elaboration). The effect of traditional midwives on people's decisions to use contraceptives and their continued use in rural Country X has never been evaluated (unanswered questions).
- In addition, this problem needs to be studied in the context of previous studies about IUD insertion performed by rural midwives versus insertion by physicians and trained nurse-midwives.

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## Justification

- The justification of the research topic is an important part of any research proposal.
- Research is often expensive and time consuming, and most funding agencies are reluctant to support studies unless the results have direct program implications.
- When funds are limited (as they almost always are), it is especially important for the research investigator to justify the proposed study carefully.
- In doing so, the investigator should place himself or herself in the position of the approving official and should consider what criteria would be used to select the study if there were funds to support only one of several proposed studies

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- In writing the justification, it is usually helpful to consider the following questions and then arrange the answers to these questions into a few concise paragraphs:

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- **Is the problem a current and timely one?** In other words, does the problem exist now? Current problems are more likely than past problems to receive funding
- **Does the problem have life-threatening or serious morbidity consequences?** Poor surgical technique during sterilization can have life-threatening or serious morbidity consequences for the patient, whereas occasional spotting from IUD use generally does not have serious consequences
- **Does the problem affect, or potentially affect, a large number of people?** Some problems, such as thromboembolism from contraceptive pill use, are life threatening, but of all the people who use oral contraceptives, relatively few are affected. In countries where sterilization is widely used, other problems, such as anesthesia overdose, tetanus, and intraperitoneal hemorrhage, may affect a large number of people
- **Does the problem relate to on-going program activities?** That is, does the problem have implications for current programs? For example, a study comparing failure rates and complications of different IUDs is not likely to have major program implications in a country where the IUD is not commonly used

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- **Does the problem have broad social, economic, political, or health implications?** Some studies may impact many different activities. For example, using nonmedical personnel to provide contraceptive methods may lower maternal mortality and fertility rates and thus have broad social, economic, and political ramifications
- **Is the problem viewed as a concern by many different people?** A research problem that evokes the concern of many different people—administrators, politicians, health professionals, the general public—is more likely to receive priority funding than one that only a small group of researchers view as a concern
- **Have many studies already addressed the problem?** For some reproductive health issues study has been extensive, and much is already known about the etiologies of the problems. For example, the complications and failure rates of different IUDs have been widely studied. Would another IUD study add significant new information?

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**Example**

- The Ministry of Health and the Women's Development Movement have completed negotiations with an international donor for a \$5 million loan that will be distributed over the next 5 years. The funding will be used to double the existing network of family planning clinics in an effort to increase contraceptive prevalence from 12% to 35% by 19%. Considerable controversy exists over whether or not to promote the use of IUDs in existing and future rural and urban family planning clinics because IUD use is associated with an increased incidence of pelvic inflammatory disease (PID) (Faulkner and Ory, 1976; Kaufman et al., 1980; Vessey et al., 1981). Two studies were conducted in Country X — one at the National Teaching Hospital in 1980 and one in three provincial hospitals in 1981. The findings indicated that between 28% and 35% of women examined in the obstetrics and gynecology wards had PID and suggested that PID may be a prevalent condition. PID is expensive and difficult to treat in most clinics. If untreated, PID can lead to infertility, a problem that is thought to be widespread in certain areas of Country X.

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**Contd.**

- Thus, before the Ministry of Health can promote IUD use in these areas, methods for decreasing IUD-associated PID need to be identified. If IUDs can be used safely and if one-third of the new users of contraceptives used IUDs, the costs associated with family planning visits for resupply of oral pills and other contraceptives could be reduced by as much as 50%. Service providers could spend more time promoting family planning among unserved high-risk women and thus increase the likelihood of achieving the country's goal for contraception

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**Contd.**

- A recent study conducted in the United States concluded that IUDs were associated with PID only at times of insertion or reinsertion (Burkman et al., 1981). Consequently, antibiotics given prophylactically to women at the time of IUD insertion may decrease the incidence of IUD-associated PID. However, no research has been conducted to test this hypothesis. The randomized clinical trial to be described is designed to test this hypothesis in rural and urban service delivery clinics in Country X.

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**Goals and Objectives**

- Before a study is actually designed, the study's ultimate, long-term, public health goal and its immediate, specific research objectives are written
- Ultimate goals should be stated in terms of the potential impact or public health purpose of the study or service delivery program
- Although goals are not as detailed as research objectives, they must be clear.

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**Goals are stated in terms of:**

- Broad social, economic, or health concerns.
- Change in policy decisions, service delivery programs, or individual health behaviour.
- Populations that may be affected
- Research objectives describe what will be demonstrated, tested, evaluated, confirmed, or compared

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**Research Questions or Hypotheses**

- All proposals should contain a formal and explicit statement of the research question(s) to be studied or the research hypothesis(es) to be tested
- Whether to use questions or hypotheses depends on the type of research
- Exploratory or descriptive epidemiologic research does not involve hypothesis testing; it is based on underlying questions
- The research questions must be formally stated with clarity, specificity, and appropriate inclusiveness

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**Example**

- Why does Village Y have half the fertility rate of other populations in the region? Is the lower fertility rate due to more effective use of contraception, different breast-feeding practices or marriage patterns, or other unspecified social practices?
- What are the levels of maternal and infant mortality in major cities of Country X?

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**Hypothesis**

- A hypothesis is a statement (not a question) about an expected relationship between one or more independent variables and one dependent variable.
- The statement should proceed logically from the prior problem identification.
- In addition to stating the hypothesis(es), the proposal should also indicate:
  - Under what conditions the hypothesis is expected to be true
  - All potential intervening variables that may affect the dependent variable.
  - Operational definitions for all variables included in the hypothesis(es).

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**Example**

- There is no significant difference in contraceptive use at first intercourse between children who receive a sex-education course before entering their teens and those who do not receive such a course
- The fertility rate among catholic women in country X is the same as that of non-Catholic women
- There is no significant difference smoking rate between pregnant women who attend the prenatal clinic in District X than among women who do not attend

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