P R O T O C O L

FOR HOSPITAL-BASED DESCRIPTIVE STUDIES OF MORTALITY, MORBIDITY RELATED TO INDUCED ABORTION

WHO PROJECT NO. 86912

TASK FORCE ON SAFETY AND EFFICACY OF FERTILITY REGULATING METHODS

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This protocol is a model for hospital-based descriptive studies of mortality and morbidity of induced abortion and its impact on resources for health care services. The protocol should be modified according to characteristics and needs of participating countries.

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1. RATIONALE

1.1 Justification

Induced abortion contributes to high rates of maternal mortality among women around the world and continues to be an important cause of serious morbidity among women of reproductive age.

Recently a meeting to identify research priorities on induced abortion was arranged by the Task Force on Safety and Efficacy of Fertility Regulating Methods. Both the meeting participants and the Steering Committee of the Task Force recognized that illegal abortion remains a major problem. Therefore, it was recommended that the aim of future studies should be to obtain information which would assist in reducing morbidity and mortality from illegally induced abortion.

In countries where abortion is strongly restricted or totally illegal (62 countries in 1982), many women resort to various methods of self-induced abortion and abortion by untrained illegal practitioners, which results in high mortality. The abortion methods related to highest complication rates also place the greatest drain on hospital resources. Obtaining reliable information on illegal abortion complication rates and the public health implications is difficult. Both women who obtain abortions as well as abortion providers are often unwilling to report illegally induced abortion. However, in some countries where abortion is illegal, but informally accepted and widely practised, it has been possible to conduct studies to evaluate the health and health service implications of the practice.

Previously, WHO's Task Force on the Sequelae of Induced Abortion developed and tested a method of investigating the health consequences and cost of illegally induced abortion and produced a manual on the subject. The study was conducted in Turkey, Nigeria, Venezuela and Malaysia during 1976-78. At that time abortion was illegal in these countries. The main objectives were to test a research technique for the evaluation of the impact of illegal abortion on the hospital services and to test the feasibility of a community based study. A special effort was made to ensure the use of appropriate data collection instruments and well-trained personnel.

The study showed that the results from one setting may not be applicable to other settings since for example the "typical" abortion case in Nigeria is different from the "typical" case in Turkey. Also the difficulties in obtaining valid field data on illegally induced abortion were quantified, and varied greatly in different settings. In some countries it was clear that any attempt to obtain valid data through field surveys would be futile, whereas in selected other countries, field surveys might provide some useful information.

The completed 4-centre study did demonstrate that in selected settings, with a carefully designed protocol, useful information could be collected on the health consequences and health resource implications of illegally -induced abortion. The study described in this protocol is thus modelled on the previous study, but includes modifications as a result of "lessons learned".

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It would be most desirable to conduct population-based studies which would try to show the impact of abortion on female mortality and morbidity in various age groups.

In the recent WHO meeting on maternal mortality, it was, however, clearly pointed out how difficult it is to conduct such a study since it would require quite reliable systems of registration of population events, such as death or disease. This is the main reason for not conducting area-based studies, but hospital-based.

1.2 Other recent similar studies

a) WHO Task Force on the Sequelae of Abortions

"Illegal abortion: An attempt to assess its cost to the health services and its incidence in the community" (Accepted for publication)

Participating centres included three hospitals in Ankara, Turkey; three hospitals in Ibadan, Nigeria; one hospital in Caracas and one in Valencia, Venezuela; and two hospitals in Kuala Lumpur, Malaysia.

All women admitted in these hospitals with a diagnosis of abortion during the study period (varied duration in 1976-1978) were included in the study. Their total number was 5429. On admission all abortion cases were classified as induced or spontaneous by the admitting physician on the basis of the information provided by the woman herself and on the basis of a set of medical criteria.

The proportion of induced abortion classified as "certain", "probable" and "possible" varied widely from setting to setting. These differences apparently reflect both real differences in the epidemiology and differences in reporting based on the social acceptability of abortion in various countries. This study also showed that the sociodemographic variables characterizing induced vs spontaneous abortion cases varied from country to country. In all centres, induced abortion cases required longer hospitalization and twice as much blood units and the cost of medication was also higher than with spontaneous abortion cases. The second phase of the study tested the possibility of obtaining valid field data on abortion through home interviewing. Women hospitalized for abortion were interviewed six months later in their homes. This exercise showed a degree of under-reporting of abortion that varied widely among centres, even among women who had admitted illegal abortions at the time of hospitalization.

b) Binkin NJ, Burton MM, et al

"Women hospitalized for abortion complications in Mali" International Family Planning Perspectives Vol. 10, No. 1, March 1984, p. 8-12.

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One year prospective observational study in 15 hospitals and maternity clinics in Mali.

Women who were hospitalized for complications of induced abortion tended to be young, unmarried students. They had more major complications; they required greater use of antibiotics, oxytocics and anesthetics, more surgical procedures and longer hospital stays than did women who had spontaneous abortions. The death-to-case rate was nearly five times higher among women hospitalized with complications of induced abortion than among women hospitalized following spontaneous abortion. Although women with complications of induced abortion accounted for only 0.5 percent of total obstetric admissions in the capital city of Bamako, they accounted for at least four percent of maternal deaths.

c) Aggarwal VP, Mati JKG

"Epidemiology of induced abortion in Nairobi, Kenya"
J. Obst. Gyn. East. Cent. Africa, 1:54:1982 p. 54-57.

A prospective study of 610 women admitted with abortion to Kenyatta National Hospital in 6 months in 1981.

62% of total abortion admissions were induced or likely to be induced. They were more common in single adolescent girls who had little or no knowledge of contraception. Twenty five per cent of the cases were terminated by non-medical personnel. Mean hospital stay in the induced group was 98 hours as compared to 32 hours in the spontaneous group.

d) Khan AR, Begum SF et al

"Risks and costs of illegally induced abortion in Bangladesh"
J. Biosoc. Sci. (1984) 16: 89-98

A prospective study of 2014 women admitted to Dhaka Medical College Hospital in two periods from 1977-1978 and 1979-1980 with the diagnosis of incomplete, illegally induced abortion.

Women with low complication rates more often had abortions induced by medical practitioners. These women were younger, of lower parity and better educated than women having abortions initiated by other practitioners. Poorly educated women from slum areas almost always had abortion induced by a non-medical practitioner through the insertions of a solid object. These women experienced high complication rates and often required hysterectomies. This group also had high mortality rates. The drain on hospital resources needed to treat these abortion patients was great.

e) Pongthai S, Phuapradit W, Chaturachinda K.

"Illegally induced abortion: observation at Ramathibodi Hospital"
J. Med. Ass. Thailand Vol 67, Suppl. 2, Oct. 1984, p. 50-52.

Data on 865 illegally induced abortions seen at Ramathibodi Hospital during 1969-1977.

Data were extracted from questionnaires and hospital records. The data represent, at the least, the minimum figure of illegally induced abortion. The women were married and between 20-24 years of age as an average. Sepsis and death were the main complications resulting in high cost of treatment.

2. OBJECTIVES OF THE STUDY

1) Within a hospital setting to investigate morbidity and mortality resulting from induced abortion .

2) To estimate the medical and economic resources spent on treatment of abortion complications.

3) To characterise women with morbidity and women who die as a result of abortion (in the hospital setting) in order to try to identify risk factors that might suggest preventive measures. (This latter objective which includes KAP (contraceptive knowledge, attitudes and practice), is desirable but optional for participating countries).

3. GENERAL STUDY DESIGN

3.1 Study population

All women admitted to the hospitals in question with a diagnosis of abortion will be included. As the clinical manifestation of abortion complications are heterogenous and may result in hospitalization in departments other than department of OB/GYN, emergency admissions for women in the pertinent age-interval to departments of internal medicine, surgery and infectious diseases and others will also be checked. It is realized that the provisional admission diagnosis in some of these cases will not include a suspicion of induced or spontaneous abortion. Therefore, each case where the admission diagnosis is potentially compatible with any serious abortion complication (e.g. sepsis, acute renal failure, peritonitis, pelvic venous trombosis), will be checked for the possibility of being associated with a recent induced or spontaneous abortion. Also, in the event of admission to the departments of OB/GYN, the admission diagnosis may not always refer to abortion, but be phrased as salpingitis, PID, pelvic peritonitis, genital trauma, excessive bleeding etc. Therefore, for cases where the admission diagnosis is compatible with complications from an induced or spontaneous abortion, an attempt will always be made to elucidate if the condition in fact was proceeded by an abortion.

The diagnosis regarding abortion will be classified into four categories: "Certainly" induced, "probably" induced, "possibly" induced and spontaneous abortion. The classification is based on the interview and on the physician's examination according to the following criteria:

1. "Certainly" induced abortion

Cases are classified as "certainly" induced abortion when the woman herself provides this information, or when such information is provided by a health worker or a relative (in the case of the woman dying) when there is evidence of trauma or of a foreign body in the genital tract.

2. "Probably" induced abortion

Cases are classified as "probably" induced abortion when the woman has (1) signs of abortion accompanied by sepsis or peritonitis and, (2) the woman states that the pregnancy was unplanned (she was either contracepting during the cycle of conception or she was not contracepting because of reasons other than desired pregnancy).

3. "Possibly" induced abortion

Cases are classified as "possibly" induced abortion if only one of the conditions listed under 2 above is present.

4. "Spontaneous" abortion

Cases are classified as "spontaneous" abortions if none of the conditions listed under 1-3 above is present or if the woman states that the pregnancy was planned and desired.

On the woman's discharge from the hospital, the case-records will be reviewed regarding discharge diagnosis, surgical treatment, medications including transfusions, and the case's abortion history and the classification of the abortion will be reassessed.

3.2 Data to be collected

i From the interview:

1) Demographic characteristics: age, domicile, marital status, occupation, husband's occupation, education, ethnic group, religion.

2) Present pregnancy history, including date of last menstrual period.

3) Previous pregnancy history including deliveries and abortions (induced (legal, illegal) and spontaneous).

4) Contraceptive history of last year and at time of conception. KAP (knowledge, attitudes practice of contraception), availability of family planning services, male knowledge and attitudes will be optional.

5) Woman's own report of abortion, whether it was spontaneous or induced, and abortionist, cost of the procedure, if applicable, as well as type of procedure, timing of procedure and on-set of symptoms, use of antibiotics adjunct to procedure.

6) Reason for termination of pregnancy, if applicable.

7) If the pregnancy was planned or unplanned (according to 3.2 i 2) and 3.2 i 4) and if the pregnancy was wanted or unwanted.

ii From the hospital records, from the physician:

1) Outcome of physical examination (signs of genital trauma, evidence of manipulation or foreign body, pelvic or general peritonitis)

2) Complications and course of the disease (e.g. hemorrhage, sepsis, death)

3) Treatment (e.g. medication including antibiotics, blood transfusions, hysterectomy and other surgery)

4) Duration of stay in hospital

iii Other information to be obtained from the hospital

1) Number of blood transfusions and laparotomies consumed at the hospitals and their department of OB/GYN and amount of antibiotics used at the department of OB/GYN during the study period.

2) Numbers of all women admitted to the hospital and to the dept. of OB/GYN during the study period.

3) Number of laparotomies and specifically hysterectomies at department of Ob/Gyn during the study period.

4) Number of deliveries at the hospital during the study period.

5) Numbers of in-hospital maternal deaths by cause during the study period.

iv Other information

If feasible, information should be obtained about the length of time, the women are unable to work after discharge from the hospital. This might be done by recording duration of recommended sick leave at discharge from the hospital and/or by recording duration of sick leave at revisits at the hospital, or by providing the women with a prepaid postcard that they would return later, indicating date of return to work and if they are healthy or not.

4. ETHICAL CONSIDERATIONS

Because of the sensitive nature of the study, the reports will remain confidential and every effort will be made to make them anonymous. The interview will be conducted as privately as possible, and at a time convenient for the study subject. The interviewers will be women who have specific training in the conduct of sympathetic interviews. Before the interview, the nature of the study should be explained to the subject, and her permission should be obtained to continue with the interview. This study does not involve any invasive or medical procedures. After completion of data collection for women in the study, information that would allow women to be identified individually will be removed from the questionnaire.

5. DATA ANALYSIS

All the questionnaires from the participating centres will be sent to WHO, (identifying subjects by number only) for compiling, checking, data entry and analysis of the data. Copies of questionnaires should be kept by the local investigators.

Analysis proposed:

1. patients with abortion as a proportion of all hospital admissions and OB/GYN admissions.
2. percentage of complications and deaths amongst women with abortion in relation to type of abortion.
3. number of deaths attributable to the various categories of abortion relative to other maternal deaths (mortality)
4. characteristics of women, by type of abortion
5. association between type of abortion and KAP contraception
6. description of various cost elements of hospitalization, length of hospital stay, medications used, blood units transfused, number of laparatomies for the abortion cases relative to the corresponding consumption of the hospital and the department of OB/GYN.
7. Among abortions known or thought to be illegally induced ("certain" induced abortion): complications by method, gestational age, use of concomitant antibiotics, type of abortionist.

6. PERSONNEL INVOLVED

At the central level at WHO, Geneva there will be a study coordinator, who will site visit the centres as needed. In every participating centre/hospital there will be a principal investigator/study coordinator who will locally involve the relevant staff working normally at emergency rooms and gyn/surgical wards. The number of interviewers at each center will depend on the estimated numbers of subjects recruited monthly. The interviewers have to be selected and trained carefully by local investigators based on the criteria explained in the annex of this protocol.

7. SELECTION OF STUDY CENTRES

Priority will be given to centres in the developing countries where safe abortion is not readily available and where there is at least some recognition of the public health importance of illegally-induced abortion. Additional criteria to participation include committed investigators and adequate hospital records. Investigators' meeting will be arranged prior to starting the study.

8. PILOT STUDY

To test the questionnaires and to evaluate the feasibility of the study (including recruitment rates and quality of hospital records etc.) a pilot study will conducted at each centre. The pilot-phase should focus on the recruitment rate of cases of abortion, quality of hospital records, cooperability of hospital staff and cases as well.

9. DURATION OF STUDY

The duration of the study will have to vary according to the needs of the participating centres, it is anticipated that the average time for the study will be approximately two years.

10. QUESTIONNAIRE AND GUIDELINES FOR INVESTIGATORS

A "master" questionnaire is enclosed which will have to be adjusted by the investigators in each participating country to comply with their aims and social and cultural circumstances. Guidelines for the investigators will have to be developed within each participating country according to local conditions and specific needs.

11. ANTICIPATED DIFFICULTIES AND PROBLEMS

A main component in this study is to distinguish between spontaneous and induced abortion among women with abortion-related complications. The scheme used to obtain this distinction (Section 3.1) has been used in various studies and populations. In countries where the regulations of induced abortion are restrictive and the public's attitude towards induced abortion is non-permissive, it can be apprehended that few women who had an induced abortion will admit this. Because the scheme used to determine whether the abortion was spontaneous or induced contains an element of admittance from the women of induction of abortion, the estimates of this study on the occurrence of complications of "certainly" induced abortions will probably be conservative in countries with a non-permissive attitude towards abortion.

Furthermore, scientific data are lacking from developing countries regarding the occurrence of complications to spontaneous abortion. Complications of abortion is an important component of the scheme used to categorize the abortion as "probably" or "possibly" induced abortion (Section 3.1). Therefore, the occurrence of complications after spontaneous abortion can lead to an over-estimation of complications attributable to "probably" or "possibly" induced abortion or both.

(Annex to follow
TABLE 1 - CRITERIA FOR
CLASSIFYING ABORTION CASES)