MANUAL FOR THE INVESTIGATION AND DIAGNOSIS OF THE INFERTILE COUPLE

WORLD HEALTH ORGANIZATION

Special Programme of Research, Development
and Research Training in Human Reproduction

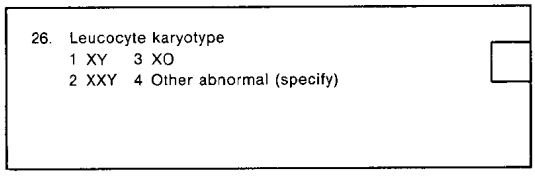
WORLD HEALTH ORGANIZATION

INVESTIGATION AND DIAGNOSIS OF THE INFERTILE COUPLE STUDY NUMBER: 78923

CORRIGENDUM

Data Collection Form.

1. **Form 4.1F question 4,** 'other laboratory tests and results' should have been printed in UNSHADED AREA; therefore this question may be answered for every subject.
2. **Form 7.1M question 5,** 'other laboratory tests and results' should have been printed in UNSHADED AREA; therefore this question may be answered for every subject.
3. **Form 7.2M question 26,** 'leucocyte karyotype' should read:



CONTENTS

MANUAL FOR THE INVESTIGATION AND DIAGNOSIS OF THE INFERTILE COUPLE

1. Introduction

This manual is intended for use with the forms and flow charts for the investigation and diagnosis of the infertile couple. It is of utmost importance that each investigator participating in the programme read this manual carefully prior to the start of the study, and refer to it routinely as questions arise during the study.

The purpose of this manual is to attempt to unify and standardize both the minimal and optimal diagnostic procedures which lead to the effective management of the infertile couple.

If one wants to compare the results reported from different centres, a uniform approach needs to be adopted for at least the following procedures: the diagnostic selection of subjects for treatment of infertility; the choice of therapy; the treatment scheme; the monitoring of therapy; and the parameters of follow-up. Additionally, comparison of the results obtained in various groups of patients at the same centre, and more so, of patients treated at different centres is only possible if a well-defined and reproducible diagnostic classification and treatment method has been used.

1.1 The Forms

The instructions contained in this manual are to be used in conjunction with the forms designed for this study. The forms have been prepared with two purposes in mind—firstly, to serve as data collection instruments for this WHO sponsored study, and secondly, to serve as the clinical records for the patient if the physician so desires. Care has been taken to leave spaces for details which the physician may wish to include in the patient record.

The form booklet consists of duplicate copies of each form, to be completed by placing carbon paper between the two pages. **The copy of each page is retained at the centre, while the original is sent to WHO.**

1.1.1 *Purpose of the Forms*

The following is a list of the forms to be used for the study, and the general purpose of each.

Screening form: (Not in booklet but in separate pads).

Purposes: (a) to determine the eligibility of patients for participation in the study

(b) to determine the number of patients attending the clinic who complain of infertility.

Form 1 – Registration form and history of couple

Purpose: to register the couple as study participants, and to obtain background and general characteristics such as age, duration of marriage/union, duration of infertility etc.

Form 2 – History of female partner

Purpose: To obtain information regarding the medical history of the female partner, related to both infertility and general health.

Form 3 – Physical examination of female partner

Purpose: To obtain detailed information regarding physical signs and symptoms which may relate to infertility.

Form 4 – Diagnostic procedures for female partner

Purpose: To obtain detailed information of diagnostic value for infertility.

Form 5 – History of the male partner

Purpose: To obtain information regarding the medical history of the male partner, related to both infertility and general health.

Form 6 – Physical examination of the male partner

Purpose: To obtain detailed information regarding physical signs and symptoms which relate to infertility.

Form 7 – Diagnostic procedures for the male partner

Purpose: To obtain detailed information of diagnostic value for infertility.

1.1.2 *Shade Coding of the Forms*

The printing on the forms for this project has been shade coded in order to:

1) facilitate completion of the forms and
2) avoid spending time asking the patient questions which are not applicable.

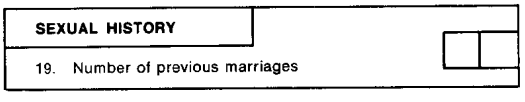
The coding scheme is as follows:

1. *Questions* printed in UNSHADED AREAS are to be answered for every subject.
2. *Questions* printed with HATCHING (////////////////) are optional, and may be completed at the discretion of the physician.
3. *Responses* printed in UNSHADED AREAS indicate that the interviewer should STOP asking further questions in the particular question group (which will be in SHADED AREAS), and continue with the next question printed in UNSHADED AREAS.
4. *Responses* printed in SHADED AREAS indicate that the interviewer should continue asking further questions in the question group which are in SHADED AREAS. The interviewer should then continue with subsequent questions printed in UNSHADED AREAS.

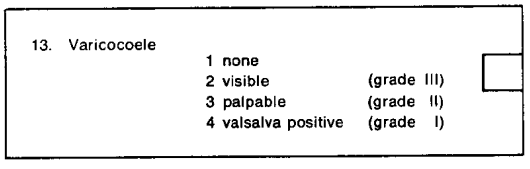
Below are examples of the coding scheme:

Examples:

Form 2.3 19
Form 5.3 16 Number of previous marriages

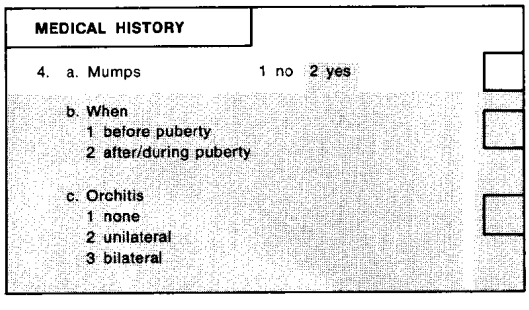


Form 6.2 13 Varicocoele
1. none
2. visible
3. palpable
4. valsalva positive



The above questions are answered for every subject.

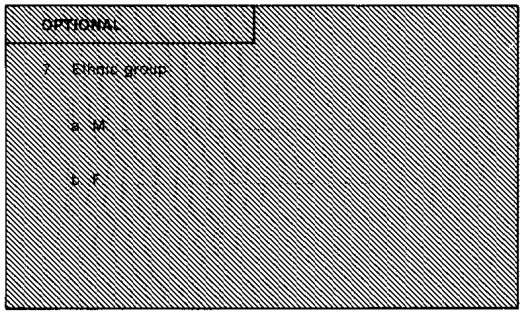
Form 5.1 4 History of mumps 1. no



In the above question, if the answer to part (1) is 'no', do not complete parts b and c and continue to the next question printed in an UNSHADED AREA.

If the answer to part (a) is 'yes', answer parts b and c and continue to next question.

Form. 1.1 7 Ethnic group



The above question is optional and is hatched.

1.2 The Flow Charts

Located at the end of the form booklet are two flow charts: 1) Flow chart for the diagnosis of infertility in the female, and 2) Flow chart for the diagnosis of infertility in the male.

The importance of these flow charts cannot be overstressed. They illustrate the diagnostic pathways which have been developed for the purposes of standardization for this and other studies dealing with infertility.

The use of these flow charts will ensure that in all centres the same symptoms and tests will result in the same diagnosis, and that for a given diagnosis, no symptom or necessary test will be overlooked. The flow charts ensure that to arrive at Diagnosis A it will be necessary to pass through points a, b, c and d. They also indicate the next stage of investigation necessary to achieve a specific diagnostic category from the results of a specific test or procedure.

AN INVESTIGATOR SHOULD INDICATE ON THE FLOW CHART FOR EACH PATIENT THE PROGRESS THROUGH THE CHART WHICH WILL EVENTUALLY REACH THE PARTICULAR DIAGNOSTIC CATEGORY.

The order in which tests and procedures are presented on the flow chart is not necessarily the same order in which they appear on the forms. The study forms are designed with the clinical situation in mind, while the flow chart is designed to achieve maximum discrimination.

1.3 Operational Working Definitions

Abnormal semen analysis: Characteristics or measurements which divert from the normal value. See *normal semen analysis* below.

Abortion: any termination of pregnancy (either spontaneous or induced) taking place during or before the 20th completed week of pregnancy or where the fetus weighs less than 500 grams.

Amenorrhoea, primary: The patient after the 18th birthday has never experienced spontaneous vaginal bleeding.

Amenorrhoea, secondary: Absence of spontaneous vaginal bleeding for 6 months or more.

Aspermia: Absence of seminal fluid.

Azoospermia: The absence of sperm in the ejaculate.

Consanguinuity: The marriage/union of two partners who are related as first cousins or closer.

Dysmenorrhoea, idiopathic, (primary or essential): Lower abdominal pain at or about the time of menses not associated with symptoms of the premenstrual tension syndrome and not associated with a demonstrable pelvic lesion.

Dysmenorrhoea, acquired (secondary): Lower abdominal pain at or about the time of menstruation associated with a demonstrable pelvic lesion.

Dyspareunia: painful vaginal intercourse.

Ectopic pregnancy: Pregnancy occurring outside the uterine cavity.

Family: Father, mother and siblings.

Galactorrhoea: is present when any fluid which is not blood stained can be expressed from the breast after firm manual pressure on the areola.

Hypospadias: A developmental anomaly in the male in which the urethra opens on the ventral side of the penis or on the perineum.

Infertility, primary: The woman has *never* conceived despite cohabitation, exposure to pregnancy, and the wish to become pregnant for at least 12 months.

Infertility secondary: The woman has previously conceived but is subsequently unable to conceive despite cohabitation, exposure to pregnancy and the wish to become pregnant for at least 12 months. If the woman has breast fed a previous infant, then exposure to pregnancy should be calculated from the onset of regular menstruation following delivery.

Live birth: Any baby born alive whether it is now living or dead.

Molar pregnancy (including hydatidiform mole, invasive mole, chorio-carcinoma): Hydatidiform change in chorionic villi involving all or part of the placenta. Fetal parts or evidence of embryo formation may or may not be present. This definition includes the recovery of malignant trophoblastic tissue from the uterus (chorio-carcinoma).

Normal menstrual pattern: Regular menstrual bleeding at intervals of not more than 35 days and not less than 21 days i.e. 28 ± 7.

Normal semen analysis: Semen analysis in which all parameters fall within the following ranges:

Volume: 1.5–6.0 mls
Motility: >40% progressively motile sperm
Viability: >60% with supravital staining
Density: $>20 \times 10^6$ spermatozoa/ml
Agglutination: <10%
Morphology: >50% normal forms
WBC's: $<1 \times 10^6$/ml

Oligomenorrhoea: Infrequent or scanty menstruation—bleeding at intervals from 36 days to 6 months.

Presumptive evidence of ovulation: The following are taken as presumptive evidence of ovulation. (1) Pregnancy (2) The presence of a corpus luteum. (3) Secretory endometirum (4) Plasma or serum progesterone greater than 5 ng/ml (15 nmol/l). (5) Pregnanediol excretion of greater than 2.5 mg/24 hours (7.5 nmol/24 h). These latter 3 parameters should be estimated 5–9 days before the anticipated onset of menstrual bleeding.

A pregnanediol excretion of between 1.5 and 2.5 mg/24 hours (4.5–7.5 nmol/24 h) and plasma serum progesterone concentration of 3–5 ng/ml (9–15 nmol/l) are suggestive of ovulation but require further evidence to confirm it.

Phimosis: Tightness of the foreskin so that it cannot be drawn back from over the glans.

Stillbirth: Any infant born dead after the 20th completed week of pregnancy weighing more than 500 grams.

Tubal patency and appearance: Tubal patency can be established by either laparosocpy and hydrotubation or by hysterosalpingography. The former technique has a lower incidence of false

negative results and provides additional information about the state of the pelvic organs (e.g. the presence or absence of adhesions).

Hysterosalpingography on the other hand gives information about the intrauterine cavity. Tubal insufflation is not a reliable way of establishing tubal patency.

2. Instructions for the Use of Study Forms

2.1 The Screening Form

This form is used to establish the eligibility for participation in the study of persons visiting the clinic and complaining of infertility. The criteria for participation in this study are as follows:

1) The couple has been infertile for one year or more during which time they have been trying to achieve pregnancy.
2) Both partners are available for interview.
3) Both partners are willing to undergo the necessary procedures once they have been explained to them.

Patients not qualifying for this study should be treated in the clinic's usual manner. The study forms may be used for the patient's clinical record, but copies should not be sent to WHO.

All Screening Forms should be retained at the centre, both for the qualifying and non-qualifying patients, as they may provide important information regarding the clinic workload, etc.

2.2 The Booklet Cover

2.3 Form 1 – Registration and History of the Couple

It is recommended that initially the couple should be interviewed together. Although it is recognized that in many instances this may not be possible, it is to be encouraged.

Form 1 — Registration form and history of couple

0 IDENTIFICATION					
a. Form code			H	Y	C
b. Study number	7	8	9	2	3

Question No.

0a–d Form code and study number are preprinted on each page.
Enter the participating centre number and couple number in the boxes provided.

预览已结束，完整报告链接和二维码如下：
https://www.yunbaogao.cn/report/index/report?reportId=5_30778