**Supplementary Information 1 – Patient consent form and questionnaire**

**Article title:** A cross-sectional questionnaire-based landscaping of female infertility reveals genital Infections as major contributor to reproductive tract anomalies, menstrual disorders and infertility

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**a) Patient Declaration/Informed Consent Form (English)**

**I declare that the information provided by me is true and correct to the best of my knowledge and belief. I provide my consent to be contacted for further clarifications/discussions.**

I have been asked to take part in a research study *"Design and development of rapid and cost-effective point-of-care, nano-based nucleic acid biosensors for prognosis, diagnosis and management of infection-induced infertility in females."* carried out by **BITS-Pilani, Hyderabad campus** in collaboration with **Curewell Hospital, Warangal**. The study team has described the following details pertaining to the research topic with special emphasis on its benefits for the maternal and child health. (The details have been explained to me in English/Telugu/Hindi).

a. **Why the study is being done?** [The study will be helpful to find out the prevalence of genital infections and its association with reproductive tract disorders including infertility in females in the region of Warangal, Telangana]
b. **What will happen to me if I participate in the study?** [Clinician will be able to diagnose the infections on time and will be able to decide the most appropriate treatment specific to a particular infection(s) which will provide effective and timely symptomatic relief and prevent worsening of the symptoms.]
c. **How long I will be in the study?** [It is going to be a one-time interaction on enrolment, where you will fill a questionnaire and provide consent to give urine/vaginal swab samples as part of routine procedure in the hospital for regular diagnosis. The leftover samples (waste) will be given to us for our study]
d. **The possible risks, discomforts, and the benefits of the study?** [Since the study involves minimally invasive techniques for self-sampling/sample collection by a trained medical technician at the hospital, there is minimal to no risk or discomfort involved. Plus, the study will be beneficial for research related to development of cost effective diagnosis methods important for maternal and fetal health]
e. **How my study records will be kept private?** [Multiple steps will be taken to ensure data anonymization/de-identification/security, such as
    1. The identities of the patients will not be disclosed in any publication/conferences/reports to funding agency/public forum or to any commercial organization.
    2. Patients samples will be double blinded and assigned codes – one at the level of clinic for the clinician and will also be de-identified and coded for research purpose. These codes will be alphanumeric in nature and assigned at hospital by the investigating clinician and will be then de-identified and coded when sent to PI's lab for research purpose.
f. **Whether the study will cost me anything?** [The patient will not be charged anything for this study]

I may contact Doctors of the research team at any time if I have questions about the research. In future I have the liberty to withdraw from the study at any time. I, hereby, give my consent to provide my details in the questionnaire and subsequently, give my consent to use the leftover urine/vaginal swab samples which are collected by the clinician as part of routine diagnosis to be used for the aforementioned research study.

| | | |
|---|---|---|
| Patient Name<br>_____ | Patient's Signature* | Date<br>_____ |
| Reviewed by<br>_____ | Reviewer signature | Date<br>_____ |

**b) Patient Questionnaire**

| For office use only |
|---|
| **Patient Details:**<br><br>**Name:**<br>**Gender:**<br>**Age:**<br>**Contact no.:**<br>**Address: _____**<br><br>**Patient ID (Hospital):** |
| **Patient ID (De-identified): (generated slip)** |

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**Questionnaire for the female patient**

## I. Personal Information

| | | |
|---|---|---|
| 1. | Partner's Age | |
| 2. | Patient Occupation | |
| 3. | Partner's Occupation | |
| 4. | Reason for the visit to clinic | |

## II. General Health Details (Female patient)

| | |
|---|---|
| Height (cms) = | Weight (kgs) = |
| Blood type = | |
| Do you exercise/workout?<br>Yes - No - | List of exercises and duration |
| Any addictions (caffeine/tobacco/alcohol/drug abuse):<br>Yes - No - | |

## III. Menstrual History

| | |
|---|---|
| 1. Age at first period? | _____yrs |
| 2. First day of your last period? _____ | Normal_____ / Abnormal_____ |
| 4. Are your periods regular?<br>Yes _____ /No _____ | Mention the gap between the periods: |
| 5. Details of menstrual flow. | Light_____ /Moderate_____ /Heavy_____ |
| 6. Duration of the flow | _____days |
| 8. Do you experience cramps before, during, or after your period? Yes ____ No _____ | If yes: Cramps are<br>Mild_____ Moderate_____ Severe_____<br><br>Medication for cramps (if taken)<br>_____ |
| 9. Do you bleed or spot between periods? | Yes _____/ No_____ |

**IV. Pregnancy History**

**a) Did you have term pregnancies previously? Yes - No-**
**If yes, then how many**
**b) Did you have preterm pregnancies/deliveries previously? Yes- No-**
**If yes, then give details of health of the delivered baby**
**c) Did you have natural abortions earlier? Yes- No-**
**If yes, then how many _____**
**d) Did you have medical termination of pregnancy (medical abortions) previously? Yes- No-**
**If yes, then how many _____**
**e) Did you have Ectopic pregnancy/tubal pregnancy previously? Yes- No-**
**If yes, then how many _____**

**V. Contraceptive / Sexual History**

| | |
|---|---|
| 1. What form of contraception do you use now or have you used in the past? (Tick wherever necessary.) | Pills / IUD / Diaphragm Rhythm<br><br>Withdrawal Foams/Jellies/Condom<br><br>Tubal ligation / Vasectomy |
| **2.** If you've ever been on oral contraceptives(pills), were your periods regular after stopping the pills? **Yes_____** **No_____** | |
| **3.** Do you time intercourse around ovulation? **Yes_____** **No _____** _____ | If yes, how? |

**VI. Fertility Treatment History**

1. Have you been treated for infertility before? **Yes_____ No_____**
   If yes, who was your physician? _____
   Diagnosed cause? _____

| **Treatment History** | | | |
|---|---|---|---|
| Intrauterine insemination | # Cycles _ | Dates / to __/ | Outcome: Pregnant/ Delivered/ Ectopic/ Miscarriage/ Not pregnant |
| Clomid/Letrozole alone maximum tablets/day? _ | | / to __/ | Outcome: Pregnant/ Delivered/ Ectopic/ Miscarriage/ Not pregnant |
| Clomid/Letrozole with intrauterine insemination | | / to __/ | Outcome: Pregnant/ Delivered/ Ectopic/ Miscarriage/ Not pregnant |
| Daily hCG injections/ intrauterine insemination maximum # vials/day? _ | | / to __/ | Outcome: Pregnant/ Delivered/ Ectopic/ Miscarriage/ Not pregnant |
| Completed IVF cycles | | / to __/ | Outcome: Pregnant/ Delivered/ Ectopic/ Miscarriage/ Not pregnant |
| Frozen embryo cycles | | / to __/ | Outcome: Pregnant/ Delivered/ Ectopic/ Miscarriage/ Not pregnant |
| Canceled IVF attempts | | / to __/ | |
| Any other treatment? (Describe) | | | |
| **Current Diagnosis (Tick whichever is applicable):**<br><br>**1. Amenorrhoea/Dysmenorrhoea/Irregular periods/Spot bleeding** | | | |

**2. Abortions/MTP**

**3. PCOD(PCOS)/ PID (Pelvic Inflammatory Disease)/ Endometriosis**

**4. Hyperthyroidism / Hypothyroidism**

**5. Do you experience any of the following symptoms (Tick whichever is applicable):**

**a) Vaginal Itching/burning. (Yes- No- )**

**b) Inflammation or soreness of vagina (Yes- No- )**

**c) Vaginal Discharge (Yes- No- )**

**d) Painful micturition (pain during urination): (Yes- No- )**

**e) Pain during vaginal sex: (Yes- No- )**

**f) Vaginal bleeding or spotting during vaginal sex: (Yes- No- )**

2. Any previous history of following ailments? (Tick whichever is applicable)

| | | | |
|---|---|---|---|
| High Blood pressure/ Low Blood pressure | Diabetes | Epilepsy | Vertigo |
| Heart diseases | Neurological Conditions | Kidney diseases | Liver diseases |
| Hyperthyroidism/ Hypothyroidism | Chronic Bronchitis | Chronic Migraines and headaches | Bowel irritation |
| Urinary tract infection | Gonorrhoea | Chlamydia | Syphilis |
| Hepatitis | Tuberculosis | Measles | Pneumonia |
| Sexually Transmitted Diseases (HIV, HPV, HCV) | Vaginal Candidiasis | Trichomoniasis | Cancers/Tumors |

Any allergies (Food allergen/Environment allergen/Drug/ Antibiotic allergens/autoimmune disorders)
Yes- /No- _____Mention the name_____

3. What drugs are you taking as part of current treatment procedure?

| | |
|---|---|
| Letrozole (Femara) | Clomiphene citrate (Clomid) |
| hCG (Profasi, Pregnyl, Novarel) | HMG (Repronex, Pergonal, Menopur) |
| bromocriptine (Parlodel) | Progesterone |
| Estrogen | Danazol/Danocrine |
| Prednisone | FSH (Gonal F, Follistim) |
| GnRH agonists (Lupron, Synarel) | Others? Specify. |

4. Which of the following tests have you had performed? Check all that apply and the results if known:

| | Values | Results? |
|---|---|---|
| Pap smear | | |
| Basal Body Temperature (BBT) charts | | |
| **Hormonal Tests** | | |
| Follicle stimulating hormone (FSH) | | High /Low /Normal |
| Leutenising hormone (LH) | | High /Low /Normal |
| Prolactin | | High /Low /Normal |
| Anti-Mullerian Hormone (AMH) | | High /Low /Normal |
| Estrogen | | High /Low /Normal |
| Progesterone | | High /Low /Normal |
| DHEA-S | | High /Low /Normal |
| Testosterone | | High /Low /Normal |
| Thyroid tests | Yes /No | High /Low /Normal<br><br>Are you on medication; If yes (name and dosage) |
| **Radiological/Invasive Examination** | | |
| Endometrial Biopsy | Yes /No | |
| Hysterosalpingogram (X-ray of uterus/tubes) | Yes /No | |
| Ultrasound/Sonogram | Yes /No | |
| Laparoscopy | Yes /No | |
| **Examination of genital infections** | | |
| Chlamydia/Gonorrhoea test | Yes /No | |
| Urinary tract infection. | Yes /No | If yes, provide the name of infection: |
| PPD/Quantiferon TB test/TB PCR test/TB culture test? | Yes /No | Results:<br><br>If yes, are you on TB treatment/DOTS - _____ |
| Others infections? Specify. | | |

5. **Past surgery(s)/treatment(s)**

| **Type of surgery** | **When?** |
|---|---|
| Surgery for reversal of tubal ligation? **Yes / No** | |
| Surgery for pelvic adhesions or other pelvic surgery?<br>**Yes / No** | |
| Treatment of cervix for abnormal Pap Smear? **Yes / No** | |
| Other surgeries (D&C, ovarian, appendectomy, thyroid)?<br>**Yes / No** | **Specify details:** |
| If you've had anaesthesia, have you had problems with anaesthesia?<br>**Yes / No** | **Specify details:** |

**VII. Partner's health history:**

| | |
|---|---|
| Has your partner had a semen analysis?<br>**Yes /No** | **Normal /Abnormal** |
| **Sperm Analysis stats** | |
| Sperm count:<br>Sperm motility:<br>TZI (Teratozoospermia index) levels: | UTI test:<br>White blood cells: |
| Is your partner seeing a doctor for evaluation of infertility?<br>**Yes / No** | If yes, what is the diagnosis and how is he being treated? |
| Has he ever fathered a child previously, either with you or with other women?<br>**Yes /No** | If yes, when? |
| Is your partner ever diagnosed with Tuberculosis/UTI/STD? **Yes /No** | If Yes, mention details and prescribed drugs/duration of therapy |

**VIII. Family History**

| | |
|---|---|
| **1.** Did your mother have any difficulty with conception or pregnancy or abortions or pre-term birth?<br>**Yes____ No____** | **If yes, give details.** |
| **2.** Is there a family history of infertility?<br>**Yes____ No _____** | If yes, who (list all members and relationship to you): |
| **3.** Is there a family history (mother and father side of the female patient)?<br>Bleeding tendencies / Strokes / Cancer / Thyroid Disorders / Diabetes / Tuberculosis /<br>(HPV, HCV, HIV) / Heart Disease / High Blood Pressure<br>Other (Specify) _____ | |