

State-of-the art facilities support the Institute to pursue research in various aspects of reproductive health: (i) reproductive health clinics that provide clinical material essential for research (ii) an experimental animal house that houses various species and strains of animals (iii) modern equipments and (iv) a library and information center.

10.1 Reproductive Health Clinics

The Institutes family welfare clinics provide reproductive health services to the nearby residents; which are usually from lower middle class group. The hospital based clinic, at B.J. Wadia Children's Hospital provide services to the hospital attendees. These five clinics facilitate research in the areas of fertility regulation, infertility, screening and prevention of birth defects, geriatric case, adolescence and involvement of men in reproductive health. These clinics are managed by obstetricians and gynaecologists, paediatricians, public health specialists and andrologists. They also have trained social scientists and counselors to provide counseling on various aspects of reproductive health issues. The beneficiaries of these clinics are usually screened and selected as volunteers for various research studies conducted by the institute's scientists and helps in getting the well characterized biological samples required for both clinical and basic research. The clinic staff has maintained a good rapport with these clients, thus studies requiring repeated follow-up visits are easy to undertake. In addition, these clinics also help in creating awareness about prevention of RTIs/STIs, unsafe abortions and related myths, misconceptions affecting decision making. Hence conducting longitudinal studies are advantageous in our clinical setup giving good retention rates in study cohorts.

10.1.1 Family Welfare Clinic

The clinics provide family planning services and serve as a model for integration of family planning services with other aspects of reproductive health care. Services offered routinely include creating awareness, screening and treatment of reproductive tract infections (RTIs), screening for cervical and breast cancer, colposcopy, pelvic ultrasonography for women and treatment of minor ailments for children under 5 years and adolescent girls. The women attending these clinics are then enrolled for clinical and basic research studies with their consent and in accordance with the ethical guidelines of ICMR.

During this year a total number of 5081 women attended the clinics for contraceptive advice (Cu-T 200/ Cu-T 380, OC pills and injection NET-EN) and

17 children for minor health problems. In addition 433 women collected condoms for their husbands. The social staff of the Wadia Clinic along with conducting family welfare clinic, extend their counseling support to women attending HIV OPD i.e. mothers who come for well baby clinics of hospital and who are antenatally detected to be infected with HIV. They are advised about their personal hygiene, nutrition, immunization of their child and the discordant couples are advised to use male condoms. The clinic also caters to the condom needs of these distributing 5440 pieces of condoms in the current year. Eighty six pelvic sonographies were done for various indications to women attending the clinics such as misplaced IUCD, etc.

Cervical cytology

The cytology laboratory at the Institute has been accredited for diagnostic purposes under the Indian Academy of Cytologists, for a period of 3 years w.e.f. July 30, 2005. One batch of four cytology smears was evaluated and reported for the external quality control programme under the aegis of the Indian Academy of Cytologists.

Papanicolaou smear screening: During the reporting year 1902 Papanicolaou smears (exocervical and endocervical) from 951 women were screened. Of these, 365 women were contraceptive non users (182 women from family welfare clinics - new cases and 183 women from endocrine infertility clinics) and 584 women were contraceptive users (IUCD - 297, injectable contraceptive Net-En-172, oral pills - 22, sterilization 44, condom use by male partner 45 and withdrawal method 6). The overall cytological findings were as follows: Normal/negative smears in 38.8 percent (n= 369) women, inflammation was observed in 56.2 percent (n=534) women. Abnormal cytology was observed in 24 women indicating atypia (n=15) and CIN I (n=9). Higher grade of CIN or invasive cancer was not detected during the year. The smears were also screened for detection of common RTIs/STIs (*trichomonas vaginalis*, *moniliasis*, *bacterial vaginosis*, *chlamydia trachomatis*, *actinomyces like organisms* and *cytomorphology suggestive for human papilloma and herpes simplex virual infections*). During this year the prevalence of actinomyces in Pap smear from IUCD users was observed in 4.4 percent (n=13).

As a part of the LIC of India's "Women's week celebration" a one time Pap smear screening (at NIRRH) and hemoglobin estimation (at the Haffkine Institute) were done jointly. A total of 131 Pap smears from the staff were screened. CIN I was detected in one, *bacterial vaginosis* in 12 and actinomyces in one IUCD user. Only 12 women reported that they had undergone Pap smear checking previously in their lifetime but all women said that they were not aware about the Pap smear test for early detection of cervical cancer. It is interesting to

note that in the city of Mumbai, one of the megacities of the country, the awareness about the Pap smear and its use in detection of cervical cancer, in educated and working (affording) women in one of the establishments was absent and only miniscule i.e. 12 women had undergone Pap smear screening in the past. Hence lot more work needs to be done in educating our women regarding their health and health care seeking behaviour.

Wet vaginal smear screening

During the year a total of 393 vaginal wet mount smears screening was also carried out for the detection of motile trichomonads. Trichomoniasis was detected in only one smear.

10.1.2 Infertility and Reproductive Endocrine Clinic

Clinical services were offered to 226 infertile couples and 9 unmarried girls, who presented with primary or secondary amenorrhoea with/without hirsutism and or obesity. The services provided included besides consultations and counseling, screening of cervical smears for reproductive tract infections/cervical intraepithelial neoplasia (CIN), hormone assays, ultrasound scans for ovarian morphology, documentation of ovulation and early detection of pregnancies in the females and andrological examination and semenology in the males. Of the 235 couples 47 discontinued investigations and 20 are being investigated. These couples made a total of 7462 follow-up visits for specific and routine investigations as well as for treatment.

Primary infertility was the chief complaint in 179 couples while 47 couples had 2 or more pregnancy losses. Majority of the women had regular cycles. Male factors were identified in 6.9 percent of cases, female factors in 73.2 percent, both male and female in 16.5 percent of cases while 4.1 percent of cases were unexplained. Eight women became pregnant during the course of investigation and 13 pregnancies followed correction of factors.

Majority of women presenting with regular cycles had anovulation or corpus luteum deficiency and they were induced for ovulation or correction of corpus luteum function with clomiphene citrate and/or hCG injections. Polycystic ovaries were detected by ultrasonography in 28.2 percent of regularly cycling, anovulatory women and in 54.4 percent of women with irregular cycles or amenorrhoea. These women were recruited for studies on polycystic ovary syndrome.

Premature ovarian failure was diagnosed in 16/94 (17.02%) women with irregular cycles or amenorrhoea and they were enrolled for genetic studies on premature ovarian failure.

On an average 350 ultrasound scans were done per month to monitor response to ovulation inducing agents, to detect early pregnancies, assess foetal well being in utero as well as to study uterine and ovarian morphology in women with varied endocrine disorders.

In addition, post coital tests, artificial insemination homologous, endometrial biopsies and hydrotubation were carried out as part of management. Estimation of serum gonadotrophins, androgens, prolactin by RIA were done to diagnose specific endocrine disorders and to select cases for various studies of the department.

Eighty-three infertile males were examined, investigated and treated in a specialized male infertility clinic attended by two andrologists. Men with azoospermia or severe oligozoospermia were recruited for genomic studies in infertile males. Men with mild to moderate oligozoospermia and those with normal semenology underwent further tests of sperm function and sperm ultrastructural evaluation for collaborative studies. The results so obtained helped in management and prognosis of these cases.

10.1.3 Elderly Women's Clinic

This service cum research community based clinic caters to services in the area of RTIs / STIs, menopause and osteoporosis. A total of 2556 individuals attended the clinic. Routine health services include cytology screening, ultrasonography as needed. In addition to these services, IEC focusing on dietary intake, lifestyle modification and prophylactic bone health measures to maintain bone health was imparted to volunteers undergoing bone density measurement. As part of the osteoporosis services 775 subjects, males and females, attended the clinic.

Individual & group counseling regarding menopause and osteoporosis are being held regularly at the "Elderly Women's Clinic". The clinical material for various projects on menopause research is drawn from this clinic.

10.1.4 Adolescent Friendly Centers

Two adolescent friendly centers were set up in two schools as part of project activity and these function on two days of the week for three hours or as required. A medical doctor and two social staff run these centers. IEC material on various aspects of sexual and reproductive health including nutrition is made available at these centers and in the library of these institutions. A letterbox to answer queries of these students is also put up.

During the year all adolescents enrolled (n=600) in the project attended the center for follow up on their medical examination along with their parents. Adolescents were counseled and treated for health problems like infections, menstrual disorders, and nutrition related problems and anemia. Adolescents who had psychological problems were counseled or referred when required. Adolescents approached for pregnancy tests and those found pregnant were referred to appropriate centers for abortion. Boys with single testes who were referred and operated were followed up and the parents were counseled on subsequent checkups. Over 400 queries were answered through the letter box on various issues related to sex and sexuality.

10.1.5 Genetic Counseling Clinic

Over the last one year the Genetic Research Centre has enrolled 168 new cases, which were registered, diagnosed and counseled. These included 25 cases of mental retardation, 46 cases for prenatal diagnosis, fifty six individuals having two or more abortions, 32 cases of short stature and primary amenorrhea, and 9 cases of ambiguous genitalia. Genetic test provided were Buccal smear in 20 cases, Karyotyping 56 cases, FISH studies were carried out in 35 cases (including FISH for chromosomal disorders and primary amenorhea), sperm FISH in 17 cases, T-FISH for 4 cases. Further, 504 patients had follow up visits.

In our study of molecular characterization of fragil X syndrome at 18 special schools of Bombay Municipal Corporation, we had examined and evaluated 400 cases of idiopathic mental retardation. Out of these cases, 3 patients were confirmed fragile X syndrome. These 3 families were counseled and given anticipatory guidance regarding their mental and medical health and also adolescent sexual health problem.

As part of the educational, teaching and training programme the genetic research centre imparts 10 hrs of genetic lecture series for B.Sc. and M. Sc. Shree Nathibai Damodar Thackersey nursing student as part of their curriculum. Summer trainees from different part of the states are trained in various technologies used for cytomolecular diagnosis. Genetic Research Centre also contributes to various institutional collaborative projects by providing clinical diagnosis and assistance in blood collections. Genetic Research Centre also provides in-house first aid assistance for the staff of the institute.

10.2 Institutional Clinical Ethics Committee

Clinical studies involving humans are reviewed by the Institutional Ethics Committee, as obtaining approval from the Committee is an essential prerequisite to initiation of all studies. The Committee is multidisciplinary and

multisectorial in composition with 11 members from outside the Institute. All members are fully cognizant with the prevailing local, social, legal and cultural norms. Each project is evaluated from the point of possible risk to subjects, proper justification, expected benefits, adequacy of documentation, procedures of informed consent, including appropriate translations into local languages, ensuring privacy, confidentiality and justice. The Committee also scrutinizes the competence of the investigators undertaking research work and reviews the progress of the approved study proposals and modifications, if any, introduced during the course of the studies, adverse events and results of research work.

Thirty six projects were reviewed and ongoing as well as modified projects scrutinized during the meetings held through the reporting period.

10.3 Experimental Animal Facility

The Institute has a well maintained animal facility distributed over three floors and different species of laboratory animals such as mice (904), rats (902), rabbits (158), bonnet monkeys (96) and marmosets (143) are being maintained and taken care of by qualified and trained staff regularly including weekends and holidays. The details of animals bred and supplied during the year is given in Table 21.

Table 21: Animals bred and supplied during the year (April 2004-March 2005).

Sr. no.	Species	Animals bred	Animals supplied	Total strength as on March 2005
1	Swiss mice	1688	1289	521
2	Balb/c mice	664	451	383
3	C57BLC	86	-	66
4	CD1	172	-	174
5	DBA2	9	-	12
6	F.V.B.	73	-	74
7	Holtzman rats	2041	1841	902
8	Rabbits	87	38	158
9	Bonnet monkeys	-	-	96
10	Marmosets	28	12	143

10.4 Institutional Animal Ethics Committee

The Institute is registered for breeding and conducting experiments on animals (Control and Supervision) with the Committee for the Purpose of

Control and Supervision of Experiments on Animals (CPCSEA), Ministry of Social Justice and Empowerment, Government of India (vide Registration No. 78/1999/CPCSEA dated 11 March 1999).

The Institutional Animal Ethics Committee, including CPCSEA nominee, reviews the research activities, which involve the use of laboratory animals. The Committee also ensures that laboratory animals are housed in an appropriate environment, properly taken care of and used only when other *in-vitro* methods cannot provide the desired information. In brief, the Committee ensures that the concept of 3R's - Reduction, Refinement and Replacement in the use of animals in research is followed.

During the year animals were supplied to 24 different projects approved by the Institutional Animal Ethics Committee.

10.5 Library and Information Center

The Dr. G. M. Phadke Memorial Library and Information Center houses an exclusive collection of books, journals, databases, reports etc. on subjects encompassing all aspects of reproductive health care. A collection of manuals and books on basic techniques in molecular biology, immunology, cell biology, stem cell research, bioinformatics etc. complement the subject specialties. The library is open for extended hours on all working days to information seekers. Reference, interlibrary loan, on-line and database (Medline and Popline) services are offered without any charge. Reprographic services are also available. The Institute is endeavoring to provide fully automated library, referral, and web-based services to scientists. Information on books and journals procured and services offered during the year is given in Table 22.

Table 22: Books and journals procured and services extended during the year.

1	Acquisition	
	Books	57
	Journals subscribed	100
2	Services	
	Number of users from other institutions	1,500
	Number of photocopies provided to readers	1,12,820
	Number of pages copy printed	1,29,484

10.6 Department of Biostatistics

The department takes active part in planning, conducting and analysis of clinical trials, necessary laboratory investigations and coordinates the activities of various departments of the Institute. Statistical staff are involved in the preparation of random allocation lists, designing of analysis, abstraction of salient features from protocols for the benefit of various departments, organization of reminder systems to ensure adherence to plan procedures, maintenance and initiation of corrective measures, as and when required.