

EAA Andrology Training Center
Centre Report

2016



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Director of the Centre: Prof. Mario Maggi (co-director Prof. Csilla Krausz)

CENTRE REPORT

History of Centre

The official history of the Andrology Center in Florence started in 1983 when Mario Serio, previously appointed as a Full Professor of Andrology at the University of Sassari in Sardinia, came back to Florence. Mario Serio opened an Outpatient Clinic at the Careggi University Hospital of Florence and focused his attention on male infertility. In order to introduce semen analysis in the clinic, he asked Claudio Orlando, a young biologist, to perform a two months stage in Belgium in the laboratory of Frank Comhaire in order to learn the principles of semen analysis.

When Claudio Orlando came back, the semen laboratory was started and other people joined the group between 1985 and 1990: Rosaria Casano, Anna Lucia Caldini, Elisabetta Baldi, and Csilla Krausz. The relevance and reputation of the Florentine Andrology was internationally recognized and the International Society of Andrology selected Florence as the venue of the IVth International Congress of Andrology which was held on May 14–19, 1989. In 1987, Mario Serio, after having obtained from the University a new laboratory in a new building, became the Chair of Endocrinology and in 1990 Gianni Forti was appointed as full Professor of Andrology at the University of Florence. Mario Serio was one of the founders of the European Academy of Andrology (EAA) on May 7th 1992 in Castle Elmau (Germany). EAA certified Florence as an Andrology Training Center in 1994 and Academicians from Florence directed the Academy from 1998-2006 (Gianni Forti) and at the present time (Csilla Krausz). In 1993, Gianni Forti became the Director of the Andrology Unit (Careggi University Hospital) with a clinical staff of three endocrinologists : Francesca Bassi, Angela Magini and Mario Maggi. Mario spent two years at the NIH, Bethesda in 1995-7. At the NIH, under the supervision of David Rodbard, he was involved in studies on gynecologic and andrologic actions of neurohypophyseal hormones. This research activity was continued, later on, in Florence and oxytocin receptor in epididymis became the topic of the experimental thesis of Linda Vignozzi in 2001. From the early nineties and up to now, thanks to the expertise and work of Elisabetta Baldi, Michaela Luconi, Csilla Krausz, Lara Tamburrino e Sara Marchiani, the rapid effects of progesterone on intracellular calcium accumulation, acrosome reaction and CatSper responsiveness in human spermatozoa have been elucidated. Another area of research of our Andrology laboratory is the study of sperm DNA fragmentation which was performed, since the end of nineties, through cytofluorimetry by Monica Muratori. From 2008 an outpatient service of sperm DNA fragmentation test for infertile patients is provided upon request from of clinicians. In 1996, Csilla Krausz went to Paris, in the Lab of M. Fellous/K. McElreavey, to work on her PhD project dealing with the role of Y chromosome microdeletions in male infertility. After her return to Florence, she continued to work on genetics of male infertility/testicular tumor/criptorchidism together with her research team (members C. Chianese, C. Giachini, F. Nuti, S. Vinci, E. Casamonti). Starting from 2003, Florence became also the venue of three editions of the Florence-Utah International Symposium on “Genetics of Male Infertility: from Research to Clinic”. Since 2004, the Krausz laboratory is the reference laboratory for the European Molecular Genetics Quality Network (EAA/EMQN Y chromosome scheme) and provides the characterization of cell lines for Y chromosome microdeletions and annual validation of selected samples for the external quality control.

In 1996, thanks to the collaboration with the cardiovascular pharmacologist Fabrizio Ledda, Mario Maggi and Sandra Filippi opened the field of experimental studies on male

impotence using cellular and animal models. This collaboration was formalized in 2004 with the establishment of the Interdepartmental Laboratory of Functional and Cellular Pharmacology of Reproduction, still active under the direction of Mario Maggi. By the time, several biologists joined the group for basic studies on male sexuality, including S. Granchi, R. Mancina, A. Morelli, E. Maneschi, I. Cellai and, lastly, F. Corcetto and C. Corno. The group is now coordinated by Paolo Comeglio. From the clinical side, an outstanding contribution was done by Giovanni Corona and Luisa Petrone that, since the end of ninetens, validated the first structured interview for erectile dysfunction, SIEDY, thanks to the collaboration with the diabetologist Edoardo Mannucci. The same group, few years later, delivered another structured interview, ANDROTEST, for the study of male hypogonadism. Male hypogonadism become, therefore, an active topic of interest, thanks also to the participation of the Florence Center (under the supervision of Gianni Forti) to the European Male Aging Study, coordinated by Fred Wu, from Manchester UK, in 2003. The collaboration is still ongoing and Giulia Rastrelli is now actively participating to the longitudinal evaluation of the database, with continuous interactions with Manchester and two fellowship stages in 2013 and 2016. Another area of clinical research is now leaded by Alessandra Fisher and deals with Gender Dysphoria (GD). An outpatient clinic for adult GD was opened in 2005 thanks to the collaboration with a team of psychiatrists (Elisa Bandini e Giovanni Castellini) led by Valdo Ricca from the University of Florence. Recently the activity in GD has been extended to adolescent GD, under the supervision of Jiska Ristori, a psychologist trained at the Gender Centre of the VU University Medical Center of Amsterdam (The Netherlands). Paraphilic disorders and other psychiatric conditions related to andrological patients are consulted by Valdo Ricca first and now by Giovanni Castellini, within the Andrology Clinic. Beside mental health professionals, active clinical and scientific collaborations with gynecologists and urologists are operating since Mario Serio establishing of an Andrologic Clinic. In particular, urologists, including Michelangelo Rizzo, Marco Carini, Mauro Gacci and Alessandro Natali, were involved in surgical retrieval of sperm, varicocele repair, treating prostate carcinoma and testicular tumors. Surgical assistance for gender reassignment was also performed by the urologists Augusto Delle Rose e Nicita Stomaci. Since 1996 up to now, there is a formal clinical collaboration with gynecologists for treating couple infertility and a gynecological and andrological simultaneous (joined) clinical interview and visit is offered to couples seeking assisted reproduction technology. The Center was originally leaded by Prof. Ivo Noci and now by Prof. Elisabetta Coccia.

In 1998, a sperm bank was established under the supervision first of Erminio Filimberti and now of Elisabetta Baldi. The bank was recognized as Regional Reference Centre for Semen Cryopreservation in 2002. In addition, the same biologists coordinated, since 2010, a biannual external quality control (EQC) programme for all semen laboratories in Tuscany Region (Italy). Selene Degl'Innocenti first and, later on, Maria Grazia Fino gave an invaluable technical support to all the semen analyses and cryopreservation activities. A dedicated outpatient session with an annual follow up for oncological patients seeking sperm cryopreservation has been organized by Csilla Krausz and Angela Magini since 2013. According to a Court modification of the Italian law for assisted reproduction, since April 2014 it is possible to offer heterologous insemination for otherwise untreatable male infertility. Hence, since that time, our Unit, under the umbrella of the local hospital, is selecting semen donors, with the medical supervision of Matteo Rossi. From 2009, Francesco Lotti is supervising a Day Service for male infertility offering hormone determination, sperm analysis and scrotal and transrectal ultrasound in the same morning. The Day Service activity was recognized by the Careggi Hospital in 2012. A similar Day Service was created in 2015 for erectile dysfunction and

another one on premature ejaculation will be available in 2017. A psychological support to couples with sexual dysfunction was offered since 2013 by a psychologist (Helen Casale) and an endocrinologist (Valentina Boddi). Based on a collaboration with paediatrician, quite recently (2016) an outpatient clinic for endocrinology of the transition from paediatric to adult age was opened under the supervision of Linda Vignozzi and Chiara Maggioli. Finally, since 2008 is active an outpatient clinic for female sexual dysfunction under the supervision of Linda Vignozzi, with the collaboration of endocrinologists (Elisa Maseroli, Sara Cipriani), gynecologists (Irene Scavello, Francesca Pampaloni) and psychologists (Egidia Fanni). Considering the broad spectrum of clinical activities, the Unit extended its name in Sexual Medicine and Andrology, under the direction of Mario Maggi, when Mario Serio retired in 2005 and Gianni Forti become the Head of the Endocrinology Unit. Sexual Medicine and Andrology Unit is still directed by Mario Maggi.

Organization of Centre

Organization charts legend: Department / Unit Structure

Unit name		
Sexual Medicine & Andrology Centre, Università degli Studi di Firenze, Dipartimento di Fisiopatologia Clinica,		
Director: Prof. Mario Maggi – Co-Director: Prof. Csilla Krausz		
Staff members		
Prof. Linda Vignozzi	Dr. Jiska Ristori	Dr. Chiara Corno
Prof. Elisabetta Baldi	Dr. Helen Casale	Dr. Francesca Corcetto
Dr. Angela Magini	Dr. Valentina Boddi	Selene Degl'Innocenti
Dr. Francesco Lotti	Dr. Sandra Filippi	Maria Grazia Fino
Dr. Alessandra D. Fisher	Dr. Paolo Comeglio	Secretary: Dr. Raffaella Gori
Dr. Giulia Rastrelli	Dr. Ilaria Cellai	
Dr. Elisa Maseroli	Dr. Monica Muratori	
Dr. Sarah Cipriani	Dr. Sara Marchiani	
Dr. Matteo Rossi	Dr. Lara Tamburrino	
Dr. Chiara Maggioli	Dr. Serena Vinci	
Dr. Giovanni Castellini	Dr. Elena Casamonti	
Clinical Services		
Outpatient Clinics for sexual medicine, couple infertility, psychopathology of sexual dysfunction, psychological counselling and behavioural therapy, gender dysphoria, female sexual dysfunctions Ultrasound penile arteries, scrotal and internal male genital tract, selection os sperm donors FNA/TESE		
Contribution to EAA training program		
Diagnosis of infertility Ultrasound of male genital tract Doppler ultrasound of penile arteries Counselling of infertile couple Cryopreservation of sperm Semen analysis Sexual Medicine Genetics of male infertility Ethics in Andrology		

Educational activities

The Unit is part of a PhD program, training PhD students with an academic background in biotechnology, biology or medicine.

The Unit is involved in the Residency Program of the School of Endocrinology for post-graduated in Medicine.

Since the last site visit, occurred in May 2010, the centre trained 3 fellows (Dr. F Lotti, Dr. V. Boddi and Dr. G. Rastrelli) who successfully completed the EAA Clinical Andrologit examination (respectively in 2010, 2013 and 2014) obtaining the qualification of Clinical Andrologist.

Since the year 2000, the Center regularly organizes a post-graduate Master Course on Sexual Medicine and Andrology, training specialists in endocrinology, urology, gynaecology, internal medicine and general practitioners, under the direction of Gianni Forti and subsequently Mario Maggi. The educational program of the post-graduate course lasts 2 years including a 10 weeks theoretical part and a 4 weeks of tutored training in the outpatient clinic. Moreover, three post-graduate courses in Male Infertility have been organized since 2011.

The centre together with the Rome EAA center, organizes the EAA Ultrasound School on Male urogenital tract since 2015. Fellows are endocrinologists and urologists from different countries and the school is based on a theoretical course and a 4 weeks hand-on training. The final examination allows the fellow to obtain the "EAA ultrasound School" certification.

The centre is also training psychologists as psychotherapists interested in sexual medicine and gender identity disorders. Moreover, the Center regularly trains Bachelor and Master students in Biotechnology, and Laboratory technical assistance and students in Medicine for their thesis.

In the frame of the Marie Curie Network of the European Commission, entitled "Reproductive Early Research Training" (2011-2015) two ESR fellows were trained at the Molecular Genetic lab of our Centre under the supervision of C. Krausz.

Research activities

Clinical research on erectile dysfunction and hypogonadism

Since the last site visit, the clinical research in the centre further developed its expertise in male sexual dysfunctions and hypogonadism. This research area took advantage of two structured interviews published and validated by the group, SIEDY and ANDROTEST, respectively for the assessment of pathogenic components of erectile dysfunction (ED) and symptoms associated with low testosterone levels. A particular topic that has been developed is the assessment of cardiovascular (CV) risk in patients consulting for sexual dysfunction. For this specific research area, a dataset including longitudinal observations of incident major adverse CV events (MACE) during a mean follow-up of 4.3 years has been produced. Information on MACE has been obtained by the collaboration with the City of Florence Registry Office. Based on all these research instruments, several markers of increased CV risk, in men consulting for sexual dysfunction, has been identified (including impaired erection during masturbation, fatherhood, extramarital affairs, low education degree, perception of low sexual interest in the partner, impaired penile colour Doppler ultrasound parameters,

impaired response to intracavernous injection of prostaglandin E1, low testosterone, low prolactin). Overall, this research area provided useful information for early identification of men at higher CV risk and prevention of MACE in subjects with ED.

A topic of great interest in the last years in the centre was represented by the CV risk associated with low endogenous testosterone levels and with testosterone replacement therapy. In the centre, these topics have been extensively studied taking advantage of a meta-analytic approach.

The meta-analytic method have been also used for improving knowledge in the field of sexual dysfunction physiology and therapy.

Clinical research on male genital tract ultrasound

A research area that greatly developed since the last site visit deals with the study of clinical correlates of male fertility. In particular, the centre improved its expertise in male genital tract ultrasound, by acquiring standard methodology for studying male genital tract in both fertile and infertile men. Taking advantage of this novel methodology, the group has become the leader of a European multicentre study for the assessment of normal ultrasound parameters of male genital tract (EAA research project). Besides the study of male genital tract in fertile and infertile men, the centre dealt with the study of clinical characteristics of men from infertile couples, such as inflammatory markers, metabolic syndrome and sexual dysfunctions.

Clinical research of female sexual dysfunctions

An emerging research area is the study of women female sexual dysfunction. In particular, at present, the centre dealt with the development of a shorter version of the FSFI questionnaire administered in both women consulting for sexual complaints and women not suffering for sexual dysfunction. Furthermore, the sexuality in women whose partner has a sexual dysfunction has been studied. Finally, the cardiometabolic derangements in women with sexual dysfunctions and their clitoral ultrasound parameters have been studied.

Gender dysphoria in adulthood and adolescence

Next to the clinical activities, teaching and research are performed; the latter in collaboration with other gender teams at a national and international level. Our adult gender team is part of an international research project (European Network for the Investigation of Gender Incongruence, ENIGI) in collaboration with the Department of Endocrinology, VU University Medical Center, Amsterdam (The Netherlands), the Department of Endocrinology, University of Ghent (Belgium) and the Department of Endocrinology, Oslo University Hospital, Oslo (Norway). The ENIGI project is aimed to evaluate the effects of cross-sex hormonal supplementation and metabolic parameters, bone density, secondary sex, anthropometric characteristics, as well as physical and psychological well-being of GD persons (Dekker et al, 2016; Wierckx et al, 2014). In addition, the adult Gender team is part of the Italian Network on gender dysphoria (together with the Gender Identity Development Service Hospital S. Camillo-Forlanini, Rome; the Center for Reproductive Health, Department of Obstetrics and Gynecology, S. Orsola Hospital, University of Bologna, Bologna, the C.I.D.I.GeM, City of Health and Science—Le Molinette Hospital, Turin; Endocrinology and Medical Sexology, Experimental Medicine, University of L'Aquila), which is focused on the evaluation of psychobiological correlates of gender transition, as well as on transphobia and homophobia levels in general population and healthcare providers.

Our children and adolescents GD team is part of an international research project (AGIR) with the Gender Centre of the VU University Medical Center of Amsterdam (The

Netherlands) and the gender teams of Ghent, Oslo, London, Hamburg, Boston and Toronto.

Clinical trials

Since 2010 until now, the centre has been involved in several national and international multicentre clinical trials, either supported or not supported by industries. The centre contributed with relevant number of patients recruited and with high retention rates, so that it always ranked among the first enrolling centres.

Since 2013 the Center is the leading organizer of the EAA Multicenter study "Standardization of the male genital tract colour-Doppler ultrasound parameters in healthy, fertile men" (reponsible Dr Francesco Lotti)

Since 2010 onwards, the centre has been involved in the following industry supported multicentre international clinical trials:

- 1) BAY 98-7081/14694: A prospective, randomized, double-blind, double-dummy, placebo and active controlled, multicentre study assessing the efficacy and safety of the combination BAY 60-4552/vardenafil compared to vardenafil (20 mg) for the treatment of erectile dysfunction not sufficiently responsive to standard therapy with PDE5 inhibitors. Sub-Investigator, BayerHealthCare.
- 2) Premature Ejaculation-Actual Use Safety and Effectiveness Study (PAUSE). Investigator, Janssen-Cilag International N.V. An observational study
- 3) MK8692-031_A phase III, multi-center, open label, uncontrolled trial to investigate the efficacy and safety of MK-8962 (corifollitropin alfa) in combination with human Chorionic Gonadotropin (hCG) in inducing increased testicular volume and spermatogenesis in adult men with hypogonadotropic hypogonadism who remain azoospermic when treated with hCG alone.
- 4) I5E-MC-TSAT A Randomized, Double-Blind, Placebo-Controlled Parallel Study with an Open-Label Extension to Assess the Impact of Testosterone Solution on Total Testosterone, Sex Drive and Energy in Hypogonadal Men.

Since 2010 onwards, the centre has been involved in the following non-supported multicentre international clinical trials:

- 1) Registry of Hypogonadism in Men (RHYME), Clinical Research Associate, New England Research Institute, Inc. An observational study
- 2) Significance of the FSH receptor polymorphism p.N680S for the efficacy of FSH therapy of idiopathic male infertility: a pharmacogenetic approach. A phase II b, multicenter, prospective, open label, one arm, clinical trial stratified according to the patient's genotype. An investigator-started, non-sponsored trial.
- 3) Standardization of male genital tract colour-Doppler ultrasound parameters in healthy, fertile men. SUSPHeM, an EAA project. An observational study

Since 2010 onwards, the centre has been involved in the following non-supported multicentre national clinical trials:

- 1) Cardiovascular Outcome of Replacement with Testosterone (CORTe). An observational study
- 2) SIAMsO-NOI: Società Italiana di Andrologia e Medicina della sessualità Osservatorio Nazionale Outcome Ipogonadismo. An observational study

Since 2010 onwards, the centre also started non-supported single-centre clinical trials, designed and performed in the centre itself:

- 1) Effectiveness of Testosterone Replacement Therapy (TRT) on Prostatic Gland in Hypogonadal Patients Affected by Benign Prostatic Hyperplasia (BPH) and Metabolic

Syndrome (MetS). Florence-PROTEST. NCT02366975. A double-blind, Placebo-controlled Study

- 2) Vardenafil and Cognitive-behavioral Sex Therapy for the Treatment of Erectile Dysfunction (STEDOV). An interventional randomized clinical trial
- 3) Double-blind, Placebo-controlled Study on Men With Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia to Assess Changes in Pressure Flow Study and in Molecular Profile of Prostatic Tissue After 12 Weeks Treatment With Tadalafil. NCT02252367
- 4) Study of the effect of testosterone treatment on metabolic parameters and LUT function in bariatric patients. An observational study
- 5) Study of the effect of testosterone treatment on inflammatory parameters and clinical scores in patients with Crohn disease. An observational study
- 6) Study on the Effect of Combined Oral Contraceptive Therapy on Female Sexuality, Body Image and Mental Health. An observational study
- 7) Pilot Interventional Study on Clitoral Ultrasound Measures and Psychobiological Correlates of Female Sexual Function
- 8) Observational study for evaluating the effect of restoring euthyroidism on female sexual function

The following clinical trials are currently ongoing:

- 1) Effectiveness of Testosterone Replacement Therapy (TRT) on Prostatic Gland in Hypogonadal Patients Affected by Benign Prostatic Hyperplasia (BPH) and Metabolic Syndrome (MetS). Florence-PROTEST. NCT02366975. A Double-blind, Placebo-controlled Study
- 2) Double-blind, Placebo-controlled Study on Men With Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia to Assess Changes in Pressure Flow Study and in Molecular Profile of Prostatic Tissue After 12 Weeks Treatment With Tadalafil. NCT02252367
- 3) Study of the effect of testosterone treatment on metabolic parameters and LUT function in bariatric patients. An observational study
- 4) Study of the effect of testosterone treatment on inflammatory parameters and clinical scores in patients with Crohn disease. An observational study
- 5) Study on the Effect of Combined Oral Contraceptive Therapy on Female Sexuality, Body Image and Mental Health. An observational study
- 6) Pilot Interventional Study on Clitoral Ultrasound Measures and Psychobiological Correlates of Female Sexual Function
- 7) Observational study for evaluating the effect of restoring euthyroidism on female sexual function

The following supported multicentre clinical trial is expected to start enrolment within February:

- A phase III, multi-center, open label, single-group trial to investigate the efficacy and safety of MK-8962 (corifollitropin alfa) in combination with human Chorionic Gonadotropin (hCG) for initiation or restoration of puberty as assessed by increased testicular volume in adolescent males 14 to <18 years old with hypogonadotropic hypogonadism (Phase III; Protocol No. MK-8962-043-00)

Basic research on erectile dysfunction, hypogonadism and female sexual function

The laboratory basic research activities focused mainly on:

- Pathophysiology of the erectile function and investigation of the urogenital tract derangements induced by metabolic syndrome (MetS), diabetes and hypertension, by means of ex-vivo and in-vitro studies in rabbit and rat animal models

- Bladder, prostate and corpora cavernosa dysfunction in animal models, with particular focus on the effects of PDE5 inhibitors and sexual hormones on the underlying pathogenetic mechanisms
- Effect of physical activity on penile erection and peripheral vascular districts functional alterations induced by high-fat diet in an animal model of MetS
- Effect of the changing sex-steroid milieu on clitoris function in a rat model of ovariectomy
- Studies on adipose tissue dysregulation and liver dysfunction associated with MetS features, including LUTS and inflammation, focusing on the role of androgen/estrogen ratio in pre-adipocytes from visceral adipose tissue in the rabbit animal model of MetS
- Mechanisms regulating differentiation and function of gonadotropin-releasing hormone neurons in humans and MetS animal models

Molecular Genetics

1) The research activity in genetics of male infertility started in 1995 with the Y chromosome microdeletions, now a routine genetic test. Since then the laboratory is dedicated to the identification of genetic factors involved in male infertility, cryptorchidism, testis cancer and recurrent abortion. Y chromosome-linked copy number variations (CNVs) in relationship with the above pathologies represents a major area of research, also in collaboration with other centers (such as the EAA Center in Barcelona and the National Oncology Institute in Budapest) Given the specific competencies of the laboratory in Y chromosome rearrangements, the laboratory organized a multicenter study aimed at defining the role of AZFc region-linked CNVs in testis cancer. The second relevant research topic of the last 6 years has focused on on X-linked copy number. For the first time in the literature we have used a high resolution array-CGH able to identify copy number variations (losses and gains) on the X chromosome with potential effect on spermatogenesis. Three published studies provided clinically relevant data: i) a significantly higher deletion load in patients versus controls; ii) the identification of the first recurrent X chromosome-linked deletion; iii) the identification of a novel X-linked candidate gene. In the last 3 years we are focusing on exome studies in familial cases of non-obstructive azoospermia and familial testis tumors and manuscript are under revision.

2) Pharmacogenetic studies on three SNPs on FSH β (rs10835638 in position -211) and FSHR (rs6166 and rs1394205) in infertile patients under treatment with FSH have been carried out during the last 4 years with two different end-points. One study has been entirely performed in Florence and lead by C. Krausz, whereas another study has been performed in the frame of a collaborative work leaded by M. Simoni

3) Currently the "Istituto Toscano Tumori" (ITT) is financing a project for the evaluation of the effect of cytostatic therapy on the male gamete genome. As "sentinels" of the genomic effects of cytostatic therapy we are analysing prior and after therapy three molecular markers in sperm derived DNA: i) 7 selected microsatellites; ii) DNA methylation profile; iii) sperm DNA fragmentation (SDF). The ultimate goal of the project is to define reproductive safety in oncological patients and thus provide evidence based information for decision making concerning the type of conception (pre-therapy frozen/thawed spermatozoa in the context of in vitro fertilization) or

natural pregnancy (spermatogenesis is recovered in about 80% of patients after chemotherapy).

The majority of the research projects performed in this laboratory have a clear translational feature and are aimed to implement the available diagnostic tests in male infertility. Genetic studies in men with impaired spermatogenesis are relevant also for the potential transmission of genetic anomalies to the next generation through Assisted Reproductive Techniques. Studies focusing on genetic factors involved in testis tumors are relevant for the prediction of genetic risk for this disease.

Sperm & prostate biology

In the research activity on sperm biology three different topics have been developed:

- Validation of TUNEL/PI technique to detect DNA fragmentation in sperm. A study has been conducted to evaluate the predictive power of the test toward natural fertility by matching 50 fertile with 150 infertile men (male partners of infertile couples). The study revealed that a cytometric sperm population recently described by the group is able to discriminate between the two groups of men independently of age and semen quality.
- Investigation on post-translation modifications of sperm proteins. In particular, ubiquitination and sumoylation in sperm and their relationship with semen quality have been studied. In addition, several sumoylated proteins have been characterized.
- Effect of methods of sperm selection for ARTs on sperm DNA fragmentation. The study allowed to show that the very popular method of sperm selection PureeSperm results in DNA damage in sperm.

In the research activity on prostate biology two different topics have been developed:

- A study has been financed by AIRC in 2016 to evaluate the possible prediction of a series of markers found in serum, urine and bioptic specimens of Prostate cancer men. The study is ongoing.

Clinical activities

Andrology and Sexology

In 2015, a total of 2250 new referrals and 4185 follow-up visits were performed in the centre.

Clinical activities are divided into:

- 1) andrological consultations, accounting for 67.6% of clinical activity. A minor part of them includes also endocrinology consultations for endocrine conditions arisen during the andrology assessment
- 2) consultations for male infertility at the Centre of Reproductive Medicine, accounting for 21.1% of the entire activity
- 3) gender dysphoria, accounting for 3.5% of clinical activity
- 4) female sexual dysfunction, accounting for 4.9% of clinical activity
- 5) consultations for oncological patients who wish to preserve fertility, accounting for 2.3% of clinical activity
- 6) endocrinology of the transition from paediatric to adult age, accounting for 0.62% of clinical activity.

Andrological consultations performed at the Sexual Medicine and Andrology Unit are dedicated to male infertility in 28% of the patients. Among patients referred to the Sexual Medicine and Andrology Unit for male sexual disorders (72% of the andrological consultations), 58.7% are for erectile dysfunction, 37% for decreased sexual desire, 25.5% for premature ejaculation, 8.2% for delayed ejaculation and finally 12.4% for Peyronie's disease. In our clinical sample low total testosterone (<10.4 nmol/l) was found in 19.9% of the cases.

In the Sexual Medicine and Andrology Unit, an ultrasound service is active. Ultrasound is performed in the clinical management of patient referred to the Unit. In the centre, penile colour-doppler ultrasound, transrectal colour Doppler ultrasound of the male genital tract, testis colour-Doppler ultrasound, male mammary gland and thyroid ultrasounds are performed. In 2015, overall 1665 ultrasonographic exams were performed.

Furthermore in 2015, 243 verapamil intralesion injection therapies for Peyronie's disease and 162 training for intracavernosal injections of vasoactive medications (prostaglandin E1) for therapy of erectile dysfunction were performed.

Since 2010, the following new clinical activities were introduced:

- the endocrinology of the transition from paediatric to adult age, started in 2015 and with the main objective of creating a connection between Pediatric Hospital Care and Adult Hospital Care in adolescents with endocrine conditions, in particular congenital or acquired diseases of the male reproductive axis;

- "day service" for erectile dysfunction, active since 2014, aimed at completing during one morning time, the diagnostic workup (including andrological visit, penile colour Doppler ultrasound, blood sampling for evaluation of metabolic and hormonal status). In this context, if necessary, coordinated and interdisciplinary interventions are activated for a complete clinical diagnosis (for example: urological visit, psychiatric examination, electrophysiological test of pudendal nerve conduction, ECG before, during and after exercise on a treadmill or using a bicycle ergometer, Doppler ultrasound assessment of the cerebral arteries etc). During 2015, we performed 150 day service for erectile dysfunction;

- outpatient clinic dedicated to men with malignancies that, before starting treatments for cancer, are referred to our Unit for sperm cryopreservation. Since 2013, the clinical andrological assessment, performed before sperm cryopreservation is aimed at providing a proper counselling about assessment of risk for infertility, eligibility for fertility preservation method, methods and indications for assisted reproductive technology that might be needed in the future and, finally, prognosis in terms of recovery of spermatogenesis after anti-cancer therapies. This is a service complimentary to sperm cryopreservation (that is active since 1998), activated for supporting patients in obtaining correct information on fertility consequences of cancer. See the specific paragraph below for further details

- sperm donor selection, since 2014. See the specific paragraph below for further details

- outpatient clinic dedicated to Gender Dysphoria in childhood and adolescence, since 2014. See the specific paragraph below for further details

- "day service" for male infertility, already present in 2010, has been greatly developed and expanded since 2012. During a single morning, a complete clinical workup of the patient is performed (including visit, semen analysis, scrotal, external and internal genital tract ultrasound before and after ejaculation, blood venous sampling for metabolic and hormonal parameters). Whenever necessary, coordinated and interdisciplinary interventions are activated for a complete clinical diagnosis (for

example: genetic counselling and investigations, pituitary MRI, bacteriological tests for urine and seminal fluid etc). In 2015 we performed 210 day service for male infertility.

The Centre takes advantage of the collaboration with psychiatrists, who had, during 2015, 180 new referrals and 540 follow up visits for psychiatric diseases in patients with sexual disorders and for the diagnostic assessment of the patients evaluated for gender dysphoria.

Furthermore, in the Unit, a service with psychologists for couple therapy of sexual problems or for real life experience in gender dysphoria subjects is available. In 2015 the psychologists performed 405 visits.

Moreover, the Unit is involved in several international clinical trials dealing with male hypogonadal patients, erectile dysfunction patients and infertile patients (see before).

Assisted Reproduction Program

The Centre of Human Reproduction has been set up since 1996 in order to provide simultaneously andrological and gynaecological consultations for infertile couple.

After the approval of the Italian law governing assisted reproductive technology with gamete donation in 2014 and the consequent requirement to increase the clinical activity in such field, the mode for andrological consultations was modified. Andrological consultations at the Center of Human Reproduction are now performed only for newly referred patients for couple infertility. About 15-20% of the patients referred to the Center of Human Reproduction present a male factor or endocrine female factor for infertility. These patients are referred to the Sexual Medicine and Andrology Unit for proper diagnostic assessment and therapy.

In case that assisted reproductive technology with male gamete donation is planned, the andrologist assesses if the indication is appropriate (i.e. no other therapy is possible for male partner). In case that assisted reproductive technology with female gamete donation is planned, the andrologist evaluates the fertility health of male partner.

Oncological patients

Oncological patients attending the clinic for cryopreservation of semen prior chemo/radiotherapy undergo to a complete andrological clinical workup which includes standardized questionnaire, physical exam, hormone dosage, Y chromosome deletion analysis in testis cancer patients and semen analysis. A yearly andrological follow up is performed with semen analysis up to 3 years. Patients who are affected by testis cancer, haematological malignancies are invited to participate at the research project (see in the dedicated paragraph in research section before) aimed to study the genotoxic effects of chemo/radiotherapy. To date, 243 patients have been included in the study.

Sperm Donation

After the approval of the Italian law governing assisted reproductive technology with gamete donation in 2014, we started performing a clinical protocol for the evaluation of potential sperm donors. Potential donors must be aged more than 18 years. The recommended upper limit of age is 40 years. The semen sample quality must be evaluated before donation. Semen parameters should be equal to or above the 50^o percentile, according to the criteria of the WHO (2010).

Briefly, the selection procedure requires an accurate medical history, psychiatric evaluation and physical examination. Karyotype and testing for cystic fibrosis carriers

should be performed on all donors. In addition, infective diseases markers should be negative before and after 180 days of the last semen donation.

To date, we have selected 30 potential donors, of them, 16 with suitable semen parameters for continuing the selection procedure. Of them, only 3 (18.8%) were eligible for donation.

Female Sexual Dysfunctions

In 2008 an outpatient clinic dedicated to Female Sexual Dysfunctions was introduced and has been consolidating throughout the years. In 2015, 90 new admission visits and 230 follow-up visits were performed by a team composed of an endocrinologist, a gynecologist and a mental health professional (psychiatrist or psychologist). Patients are referred both from primary care settings (general practitioner) and from other specialists (i.e. psychiatrist, neurologists, urologists). As a part of an active collaboration with the Gynecology Unit, and in order to meet the growing demands of users, a service dedicated to the management of sexual dysfunction in postmenopausal gynecologic cancer patients has been recently created. Other prominent activities include evaluation of sexual symptoms in patients with eating disorders, severe obesity, neurologic diseases (i.e. multiple sclerosis), and sexual adverse effects of hormonal contraceptive therapy. Whenever appropriate in order to complete the diagnostic work-up, Doppler ultrasound of external genitals is performed, with evaluation of clitoral vascularization.

In addition to clinical activity, the Female Sexual Dysfunctions clinic members are involved in research, trials, teaching and training of medical and postgraduate students (see before).

Gender dysphoria (GD) in adulthood

The Gender Team is active since the end of 2005 and deals with different activities: diagnostics; medical, psychotherapeutic and surgical assistance during the gender transition process, research and teaching. Following the guidelines of the Endocrine Society (Hembree et al., 2009) and the Standards of Care (SOC) for GDs by the World Health Professional Association for Transgender Health (WPATH, Coleman et al., 2011), the centre works as a multidisciplinary team composed by psychiatrists, endocrinologists, psychologists, urologists and plastic surgeons.

Concerning the diagnostic part, a team, composed by a psychiatrist, a psychologist and an endocrinologist, performs an integrated evaluation (interviews and psychometric tests) following the DSM-5 (APA, 2013) diagnostic criteria. The gender reassignment process includes the gender role transition, the cross-sex hormonal therapy and Sex Reassignment Surgery (SRS), if requested.

Since the activity with GD started, the number of assisted patients progressively increased: currently, 180 Male to Female (MtF) and 85 Female to Male (FtM) gender dysphoric subjects.

Gender dysphoria in childhood and adolescence

Since 2014 a unit for atypical gender development in children and adolescents was opened in line with international and Italian recommendations (Hembree et al., 2009; Coleman et al., 2011; Fisher et al., 2014). In particular, a diagnostic process, psychological support and psycho-education are performed in order to offer proper assistance to young people with gender identity issues and their families. The service works in close collaboration with the unit for adult GD people and is again multidisciplinary being composed by a psychologist, a psychiatrist and an endocrinologist.

Since the activity started, 30 young people were seen: 15 adolescents with GD, 4 children with DG, 3 Disorders of sex development (DSD) and other cases presenting with other gender identity issues (e.g. transgender, internalized homo-transphobia) but with no GD.

Diagnostic Molecular Genetics

The diagnostic part of the molecular genetics laboratory focuses on three types of genetic factors: i) Y chromosome microdeletion analysis (AZF deletions and the newly identified Y-linked risk factor, gr/gr deletion) in infertile men with < 10 million spermatozoa/ml. The number of Y chromosome routine exams in the last 6 years were 906; ii) search for mutations in two candidate genes for congenital hypogonadotropic hypogonadism: GnRHR and FGF8. This mutational analysis has been performed in a total of 130 subjects as part of a consortium under the auspices of the Italian Society of Endocrinology; iii) analysis of the DPY19L2 gene in patients affected by globozoospermia.

The laboratory is the reference laboratory for the European Molecular Genetics Quality Network (EAA/EMQN Y chromosome scheme) and provides the characterization of cell lines for Y chromosome microdeletions and annual validation of selected samples for external quality control.

Sperm analysis & Cryobanking

The principal routine analysis of the semen laboratory are: Semen Analysis, Capacitation Tests, Biochemical Assay, Interleukin 8 Elisa Assay, Semen Cryopreservation, evaluation of sperm DNA fragmentation. The total activity remained stable during the last 5 years, and substantially unchanged as compared with 2009. The laboratory is a Regional Reference Centre for Semen Cryopreservation with a total of more than 1800 samples currently cryopreserved. Most of them regards samples from patients affected by neoplastic disease, and a minority (about 10%) from spinal cord injury patients. Also patients with oligospermia are offered cryopreservation.

In addition, two years ago the lab started a service of sperm DNA fragmentation test for infertile patients, on demand from clinical physicians. Such service (about 10 semen samples/month) is totally free and the patients are advised that the service is based on an experimental method.

The lab adheres to the external quality control, UK NEQAS, since 2005. The centre is going to organize, in collaboration with the Quality Control Unit of the hospital and the Region Tuscany an External Quality Control for sperm concentration, morphology and motility.

Name and address of Centre

Sexual Medicine & Andrology Centre,
 Università degli Studi di Firenze,
 Dipartimento di Fisiopatologia Clinica,
 Viale G. Pieraccini 6
 I-50139 Firenze, Italy
 Tel: +39 055 4271 414
 Fax: +39 055 4271 413

Type of Centre

University
 University Hospital
 Private Centre

Other (please specify) _____

1a. Director

Mario Maggi

Academician Affiliated Member Clinical Andrologist

1b. Co-Director

Csilla Krausz

Academician Affiliated Member Clinical Andrologist

2a. Clinical responsible

Linda Vignozzi

Academician Affiliated Member Clinical Andrologist

2b. Clinical responsible

Angela Magini

Academician Affiliated Member Clinical Andrologist

2c. Clinical responsible

Academician Affiliated Member Clinical Andrologist

3. Present Staff (*Senior Scientists*)

1) Name Elisabetta Baldi
 Degree Associate Professor PhD
 Speciality Biology

Academician Affiliated Member Clinical Andrologist

2) Name Linda Vignozzi
 Degree Associate Professor MD, PhD
 Speciality Endocrinology

Academician Affiliated Member Clinical Andrologist

Insert any additional staff below (if required)

MD/Biologists/Chemists

1) Name Francesco Lotti
 Degree Researcher MD, PhD
 Speciality Endocrinology
 Full time/part time Full time

Academician Affiliated Member Clinical Andrologist

2) Name Alessandra D. Fisher
 Degree MD, PhD
 Speciality Endocrinology
 Full time/part time Full time

Academician Affiliated Member Clinical Andrologist

3) Name Sandra Filippi
 Degree Biologist
 Speciality Pharmacology
 Full time/part time Full time

Academician Affiliated Member Clinical Andrologist

4) Name Paolo Comeglio
 Degree Biologist
 Speciality _____
 Full time/part time Full time

Academician Affiliated Member Clinical Andrologist

5) Name Ilaria Cellai
 Degree PhD
 Speciality Biologist
 Full time/part time Full time

Academician Affiliated Member Clinical Andrologist

6) Name Monica Muratori
 Degree Biologist
 Speciality _____
 Full time/part time Full time

Academician Affiliated Member Clinical Andrologist

7) Name Sara Marchiani
 Degree PhD
 Speciality Biologist
 Full time/part time Full time

Academician Affiliated Member Clinical Andrologist

8) Name Lara Tamburrino
 Degree PhD
 Speciality Biotechnologist
 Full time/part time Full time

Academician Affiliated Member Clinical Andrologist

9) Name Serena Vinci
 Degree PhD
 Speciality Biotechnologist
 Full time/part time Full time

Academician Affiliated Member Clinical Andrologist

10) Name Giovanni Castellini
 Degree Researcher MD PhD
 Speciality Psychiatry
 Full time/part time Part time

Academician Affiliated Member Clinical Andrologist

11) Name Helen Casale
 Degree Psychologist
 Speciality _____
 Full time/part time Part time

Academician Affiliated Member Clinical Andrologist

12) Name Jiska Ristori
 Degree Psychologist
 Speciality _____
 Full time/part time Part time

Academician Affiliated Member Clinical Andrologist

Insert any additional staff below *(if required)*

Specialists

- 1) Name
- 2) Name
- 3) Name
- 4) Name
- 5) Name

Dr. Matteo Rossi MD - Endocrinologist

Dr. Chiara Maggioli - Endocrinologist

PhD Students

- 1) Name
- 2) Name
- 3) Name
- 4) Name
- 5) Name

Valentina Boddi, MD - Endocrinologist - Clinical Andrologist

Elisa Maseroli, MD - Endocrinologist

Elena Casamonti - Biotechnologist

Chiara Corno - Biotechnologist

Francesca Corcetto - Biotechnologist

Resident Students

- 1) Name
- 2) Name
- 3) Name

Giulia Rastrelli MD, PhD - Academician - Clinical Andrologist

Sarah Cipriani MD

Nurses

- 1) Name
- 2) Name
- 3) Name

Laboratory Technicians

- 1) Name
- 2) Name
- 3) Name

Selene Degl'Innocenti

Maria Grazia Fino

Administrative Personnel

- 1) Name
- 2) Name
- 3) Name

Raffaella Gori

4. Clinical Activity

A. Outpatients: Consultations per year in the last 3 years

	2013	2014	2015
New patients	1690	1720	2250
Follow-up patients	4010	4080	4185

Type of patients in the last years (%)	2013	2014	2015
Infertility	27	26.7	27
Erectile dysfunction	54	54.3	54
Hypogonadotropic Hypogonadism	5.7	5.6	5.6
Klinefelter	3.2	3.1	3.1
Gynaecomastia	1.6	1.6	1.5
Varicocele	1.9	1.9	1.8
Cryptorchidism	0.3	0.3	0.3
Male sex accessory gland infections	2.7	2.7	2.5
Testicular tumours	0.1	0.1	0.1
Disorders of gender identity	2.4	2.8	3.5
Other	1.1	1	0.6

B. Ultrasound (testis, penile, prostate)

	2013	2014	2015
Total	1548	1520	1665
Controls			

C. Andrological surgery procedures

	2013	2014	2015
Testicular biopsies			
Varicocele ligation			
Prostate biopsies			
BPH			
Prostate cancer			
Vasectomy			
Vaso-vasostomy			
Other			

5. A. Andrology laboratory activity

	2013	2014	2015
Semen analyses	2010+ 205 sperm capacitation	2026+ 206 sperm capacitation	2250+199 sperm capacitation
Sperm antibodies	1700	1700	1850
Seminal markers	194 IL8/106 sperm DNA fragmentation	207 IL8/154 sperm DNA fragmentation	271 IL8/117 sperm DNA fragmentation

5. B. Andrology laboratory activity

Sperm banking donors Yes No

Sperm banking cancer patients Yes No

<i>If yes:</i>			
	2013	2014	2015
Number of samples cancer patients	202	178	209
Number of samples sperm donors	-	-	4

5. C. Histopathological evaluation of biopsies Yes No

5. D. Reproductive Hormones Assays Yes No

If yes please specify type of assays and number of samples in the last year
Reproductive Hormones Assays
(FSH, LH, testosterone, SHBG, prolactin)

5. E. Y chromosome microdeletions according to EAA/EMQN guidelines Yes No

34

If yes number of tests in the past year

Participation to the EAA quality control scheme? Yes No

If no, specify if available in another lab of the same hospital Yes No

Blood karyotyping Yes No

If no, specify if available in another lab of the same hospital Yes No

6. Collaborations with other Clinical Units of the University/Hospital

IVF Unit	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>
Urology Clinic	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>
Endocrine Clinic	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>
Genetics Lab/Unit	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>
Paediatric Unit	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>
Central Hospital Laboratory	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>
Private Centres	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>

If yes please specify:

- EAA Training Center of Rome, Department of Medical Pathophysiology University "La Sapienza" Rome, Italy (Prof. A. Lenzi; Dr. AM. Isidori; Dr. L. Gandini)
- EAA Andrology Training Center, Endocrinology, Andrology Unit, Department of Medicine and Applied Biotechnologies, Polytechnic University of Marche, Umberto I Hospital, Ancona, Italy (Prof. G. Balercia Department of Experimental Medicine, University of L'Aquila, L'Aquila, Italy. (Prof. EA. Jannini)
- Center of Assisted Reproductive Tecnology, Careggi Teaching Hospital (Prof. E. Coccia)
- Diabetes Agency, Careggi Teaching Hospital, Florence, Italy (Dr. E. Mannucci; Dr. M. Monami)
- Department of Anatomy, Histology and Forensic Medicine, University of Florence, Florence, Italy (Prof. GB. Vannelli; Prof. A. Morelli; Dr. M. Marini)
- Psychiatric Unit, Department of Neuropsychiatric Sciences, Florence University School of Medicine, Firenze, Italy (Prof. V. Ricca, Dr. G. Castellini)
- Department of Urology, University of Florence, Florence, Italy (Prof. M. Carini; Dr. M. Gacci, Dr. A., Natali)
- Andrology Research Unit, Centre for Endocrinology and Diabetes, Institute of Human Development, Faculty of Medical and Human Sciences, University of Manchester (Prof. F. Wu)
- Division of Endocrinology and Metabolic Diseases, Department of Internal Medicine, University of Turin, Turin, Italy (Prof. C. Manieri)
- EAA Center Fundacio Puigvert, Barcelona, Spain (Dr. E. Ars, Dr. E. Ruiz-Castané)
- EAA Training Center of Zagreb, Croatia (Prof. D. Jezek)
- National Oncology Institute, Budapest, Hungary (Prof. E. Olah, Dr, T. Vaszko)
- Center has entered into the educational program "Prevention in andrology" of the Italian Ministry of Health and the Italian Society of Andrology and Sexual Medicine (SIAMS)
- Department of Endocrinology, VU University Medical Center, Amsterdam, The Netherlands (Prof Martin Den Heijer)
- Department of Medical Psychology, VU University Medical Center, Amsterdam, The Netherlands (Prof Peggy Cohen-Kettenis)

- Department of Endocrinology, University of Ghent (Belgium (Prof. Guy T'Sjoen)
- Department of Endocrinology, Oslo University Hospital, Oslo, Norway (Prof Thomas Schreiner).
- Tecnobios (Bologna) and Demetra (Florence) but only for research purposes

7. Clinical teaching activity

Duration of training (years):

	Number
A: Trainees in the last five years	46 for the Master Course in Sexual Medicine and Fertility (4 course in the last 5 years) 16 for the Post Graduate Course on Fertility (2 course in the last 4 years)
B: Trainees who passed EAA-ESAU\exam for Clinical Andrologist in the last 5yrs	3
C: Trainees working in the centre preparing to pass the EAA-ESAU examination	3
D: PhD Students	12
E: Medical Students	12
F: Other students (MSc)	18

8. Formal Andrology teaching program

Yes

No

If yes: specify duration (years/months):

Years

Months

	Hours of formal teaching per year	Professional training (weeks/months)
Medical Students	160 hours/year	7 hours/week
PhD Students	80 hours/year	38 hours/week
Post Graduate students	80 hours/year	38 hours/week
Trainees	96 hours/year	40 hours/week
Other degrees (please specify)		

9. Research Activity (maximum 1 page)

Clinical research on erectile dysfunction and hypogonadism: 1) organic and psycho-relational correlates of male sexual dysfunction, 2) cardiovascular risk factors in men with erectile dysfunction, 3) clinical and metabolic correlates of low testosterone, 4) cardiovascular risk associated with low testosterone levels and with testosterone replacement therapy.

- Corona et al. *Eur J Endocrinol* 2011; 165 (5): 687-701 (IF 3.892)

- Rastrelli et al., *J Clin Endocrinol Metab.* 2015 Aug;100(8):3172-82 (IF 5.531)

- Corona et al., *J Sex Med* 2011; 8:2098-2105 (IF 2.844)

Ultrasound: 1) male genital tract and penile color-Doppler ultrasound evaluation in infertile and fertile subjects and in patients with sexual dysfunctions; 2) association of ultrasound features with clinical, seminal and biochemical parameters. In particular, we mainly focus on the investigation of ultrasound correlates of male infertility, sexual dysfunctions, chronic pelvic pain and on the impact of obesity and metabolic syndrome on sonographic, seminal and sexual parameters.

- Lotti et al. *Hum Reprod.* 2016 Dec;31(12):2668-2680. (IF 4.621)

- Lotti et al., *Hum Reprod.* 2015 Mar;30(3):590-602. (IF 4.621)

Female Sexual Dysfunction: organic and psycho-relational determinants of female sexual desire; sexual and psychological symptoms in patients with eating disorders (e.g. anorexia nervosa), metabolic alterations (e.g. obesity) and history of sexual trauma; effects of oral contraceptives containing androgenic progestins compared with other contraceptives on sexuality; effects of sex steroids on clitoral Doppler parameters; effect of alterations of thyroid function on female sexuality; organic and psycho-relational correlates of genito-pelvic pain/penetration disorder.

- Maseroli et al., *J Sex Med.* 2016 Nov;13(11):1651-1661 (IF 2.844)

- Maseroli et al., *Andrology.* 2016 Sep;4(5):911-20 (IF 2.515)

Gender Dysphoria in adulthood and adolescence: effects of CHT on hormonal and metabolic parameters, bone density, anthropometric characteristics, as well as physical well-being of GD persons (European Network for the Investigation of Gender Incongruence, ENIGI); psychobiological correlates of gender dysphoria, particularly in terms of body uneasiness and psychopathological symptoms; psychobiological effects of gender transition; transphobia and homophobia levels in general population and healthcare providers; Psychobiological correlates of gender dysphoria in adolescence.

- Fisher et al., *J Clin Endocrinol Metab.* 2016 Nov;101(11):4260-4269 (IF 5.531)

Basic research of hypogonadism and sexual medicine: Basic research on erectile dysfunction, urogenital tract derangements, hypogonadism and female sexual function by means of ex-vivo and in-vitro studies in rabbit and rat animal models of metabolic syndrome (MetS), diabetes, hypertension and estrogen deficiency.

- Morelli et al., *J Steroid Biochem Mol Biol.* 2012 Oct;132(1-2):80-92 (IF 3.985)

- Vignozzi et al., *Mol Cell Endocrinol.* 2014 Mar 25;384(1-2):143-54 (IF 3.859)

- Vignozzi et al., *J Sex Med.* 2014 Dec;11(12):2890-902. (IF 2.844)

Sperm and prostate biology: Validation of the TUNEL/PI technique (set up in this laboratory) to detect DNA fragmentation in sperm. A study has been conducted to evaluate the predictive power of the test toward natural fertility by matching 50 fertile with 150

infertile men (male partners of infertile couples). The study revealed that a cytometric sperm population recently described by the group is able to discriminate between the two groups of men independently of age and semen quality.

- Muratori et al., Fertil Steril. 2015 Sep;104(3):582-90.e4. (IF: 4.426)

- Muratori et al., Mol Med. 2015 Jan 30;21:109-22. (IF: 3.530)

- Tamburrino et al., Hum Reprod. 2014 Mar;29(3):418-28. (IF: 4.621)

Androgenetics: 1) the role of Sex chromosome-linked CNVs in male infertility; 2) Pharmacogenetics of FSH treatment; 3) Exome studies in familial and sporadic idiopathic secretory azoospermia; 4) Central hypogonadism; 5) sperm genome damage after cytotoxic therapy; 6) sperm DNA methylation

- Krausz C et al PLoS One. 2012;7(10):e44887 (IF 4.09)

- Lo Giacco et al J Med Genet. 2014 May;51(5):340-4. (IF 5.63)

- Chianese C et al PLoS One. 2014 Jun 10;9(6). (IF 4.09)

- Chianese et al Hum Reprod. 2013 Nov;28(11):3155-60. (IF 4.621)

10. Research Funding

Please specify the amount of available funds in the last 3 years and their source (Government, European Union, University, Local Government, Pharmaceutical Industries, Banks, Foundations....)

Year	2014-ongoing
Total amount (€)	45.000
Funding Source(s)	Bayer HealthCare - Effectiveness of Testosterone Replacement Therapy (TRT) on Prostatic Gland in Hypogonadal Patients Affected by Benign Prostatic Hyperplasia (BPH) and Metabolic Syndrome (MetS). Florence-PROTEST. NCT02366975. A double-blind, Placebo-controlled Study
Year	2015
Total amount (€)	28.000
Funding Source(s)	Merck - MK8692-031_A phase III, multi-center, open label, uncontrolled trial to investigate the efficacy and safety of MK-8962 (corifollitropin alfa) in combination with human Chorionic Gonadotropin (hCG) in inducing increased testicular volume and spermatogenesis in adult men with hypogonadotropic hypogonadism who remain azoospermic when treated with hCG alone. 4)
Year	2015
Total amount (€)	15.000
Funding Source(s)	Ely Lilly - I5E-MC-TSAT A Randomized, Double-Blind, Placebo-Controlled Parallel Study with an Open-Label Extension to Assess the Impact of Testosterone Solution on Total Testosterone, Sex Drive and Energy in Hypogonadal Men.

Year	2015
Total amount (€)	75.000
Funding Source(s)	Bayer HealthCare - Study of the effect of testosterone treatment on metabolic parameters and LUT function in bariatric patients. An observational study

Year	2016
Total amount (€)	75.000
Funding Source(s)	Bayer HealthCare - Study of the effect of testosterone treatment on inflammatory parameters and clinical scores in patients with Crohn disease. An observational study

Year	2016
Total amount (€)	20.000
Funding Source(s)	TEVA - Study on the Effect of Combined Oral Contraceptive Therapy on Female Sexuality, Body Image and Mental Health. An observational study

Year	2016
Total amount (€)	80.000
Funding Source(s)	INTERCEPT PHARMACEUTICALS (USA). Effects of chronic treatment with the selective FXR agonist obeticholic acid (OCA) on preadipocyte differentiation capacity

Year	2016
Total amount (€)	40.000
Funding Source(s)	INTERCEPT PHARMACEUTICALS (USA). Study of the effect of FXR/TGR5 dual agonist on functional and fibrotic alterations induced by metabolic syndrome in peripheral vascular districts

Year	2015
Total amount (€)	50.000
Funding Source(s)	INTERCEPT PHARMACEUTICALS (USA). Effects of therapeutic treatment with the selective FXR agonist obeticholic acid (OCA) in a monocrotaline- induced pulmonary arterial hypertension rat model

Year	2015
Total amount (€)	50.000

Funding Source(s)	INTERCEPT PHARMACEUTICALS (USA). Effects of therapeutic treatment with the selective FXR agonist obeticholic acid (OCA) in a bleomycin-induced pulmonary fibrosis rat model
Year	2015
Total amount (€)	60.000
Funding Source(s)	INTERCEPT PHARMACEUTICALS (USA). Study of the effect of INT-767 on preadipocyte differentiation capacity
Year	2015
Total amount (€)	506.000
Funding Source(s)	Italian Ministry of Instructions. Announcement for “Scientific Independence of young Researchers”. Standardization of male genital tract colour-Doppler ultrasound parameters in healthy, fertile men.
Year	2016
Total amount (€)	90.000
Funding Source(s)	AIRC - Prostate cancer and psa screening: evaluation of molecular tirage methods to detect clinically important prostate cancer
Year	2016
Total amount (€)	25.000
Funding Source(s)	IBSA - DNA fragmentation in two cytometric populations of spermatozoa: biological significance and impact on assisted reproduction outcomes
Year	2016
Total amount (€)	5.032
Funding Source(s)	ABOCA - critical revision of recent literature on male infertility
Year	2014
Total amount (€)	2.452
Funding Source(s)	University of Florence - Involvement of the sperm specific CatSper calcium channel in capacitation and in oocyte fertilization
Year	2015
Total amount (€)	2.690

Funding Source(s)	University of Florence - Search for new predictive markers of the outcomes of assisted reproductive techniques
Year	2011-2014
Total amount (€)	331.494,77
Funding Source(s)	European Commission-“Marie Curie Network: Reproductive Early Research Training” Grant number: Reprotrain /289880.
Year	2013-ongoing
Total amount (€)	90.000
Funding Source(s)	Tuscan Institute of Tumors- Evaluation of cytotoxic therapy effects on the male gamete genome

CENTRE PHOTOS

Please, include at least one high resolution photos

FULL LIST OF PUBLICATIONS (with IF) of staff members from the last 5 years

- 1) Morelli A, Filippi S, Comeglio P, Sarchielli E, Chavalmane AK, Vignozzi L, Fibbi B, Silvestrini, E, Sandner P, Gacci M, Carini M, Vannelli GB, Maggi M. Acute vardenafil administration improves bladder oxygenation in Spontaneously Hypertensive Rats. *J Sex Med* 7: 107-120, 2010.
- 2) Fibbi B, Morelli A, Vignozzi L, Filippi S, Chavalmane AK, De Vita G, Marini M, Gacci M, Vannelli GB, Sandner P, Maggi M. Characterization of PDE5 expression and functional activity in the human male lower urinary tract. *J Sex Med* 7: 59-69, 2010.
- 3) Corona G, Ricca V, Boddi V, Bandini E, Lotti F, Fisher AD, Forti G, Mannucci E, and Maggi M. Autoeroticism, mental health and organic disturbances in patients with erectile dysfunction. *J Sex Med* 7: 182-191, 2010.
- 4) Muratori M, Tamburrino L, Tocci V, Costantino A, Marchiani S, Giachini C, Laface I, Krausz C, Meriggiola MC, Forti G, Baldi E. Small variations in crucial steps of TUNEL assay coupled to flow cytometry greatly affect measures of sperm DNA fragmentation. *J Androl.* 2010 Jul-Aug;31(4):336-45.
- 5) Baldi E, Bonaccorsi L, Nesi G, Serni S, Forti G, Luzzatto L. TMPRSS2:ERG fusion gene and androgen-ablation therapy in prostate cancer. *Arch Pathol Lab Med.* 2010 Jul;134(7):964-5
- 6) Muratori M, Tamburrino L, Marchiani S, Guido C, Forti G, Baldi E. Critical aspects of detection of sperm DNA fragmentation by TUNEL/flow cytometry. *SystBiol Reprod Med.* 2010 Aug;56(4):277-85
- 7) Baldi E, Muratori M, Marchiani S, Tamburrino L, Fallet C. [Fragmentation and/or decondensation of spermatid DNA: which consequences?]. *J Gynecol Obstet Biol Reprod (Paris).* 2010 Apr;39(1 Suppl):14-6.
- 8) Corona G, Boddi V, Lotti F, Gacci M, Carini M, De Vita G, Sforza A, Forti G, Mannucci E, and Maggi M. The relationship of testosterone to PSA in men with sexual dysfunction. *J Sex Med* 7: 284-292, 2010.
- 9) Corona G, Maggi M. The role of testosterone in erectile dysfunction. *Nat Rev Urol* 7: 46-56, 2010.
- 10) Marchiani S, Tamburrino L, Nesi G, Paglierani M, Gelmini S, Orlando C, Maggi M, Forti G, Baldi E. Androgen-responsive and -unresponsive prostate cancer cell lines respond differently to stimuli inducing neuroendocrine differentiation. *Int J Androl* 33: 784-793, 2010.
- 11) Corona G, Monami M, Boddi V, Cameron-Smith M, Fisher AD, de Vita G, Melani C, Balzi D, Sforza A, Forti G, Mannucci E, Maggi M. Low testosterone is associated with an increased risk of MACE lethality in subjects with erectile dysfunction. *J Sex Med* 7: 1557-1564, 2010.
- 12) Fisher AD, Bandini E, Ricca V, Ferruccio N, Corona G, Meriggiola MC, Jannini EA, Manieri C, Ristori J, Forti G, Mannucci E, Maggi M. Dimensional profiles of male to female gender identity disorder: an exploratory research. *J Sex Med* 7: 2487-2498, 2010.
- 13) Corona G, Boddi V, Balercia G, Rastrelli G, De Vita G, Sforza A, Forti G, Mannucci E, Maggi M. The effect of statin therapy on testosterone levels in subjects consulting for erectile dysfunction. *J Sex Med* 7: 1547-1556, 2010.
- 14) Meriggiola MC, Jannini EA, Lenzi A, Maggi M, Manieri C. Endocrine treatment of transsexual persons: an Endocrine Society Clinical Practice Guideline: commentary from a European perspective. *Eur J Endocrinol* 162: 831-833, 2010.
- 15) Corona G, Monami M, Boddi V, Cameron-Smith M, Lotti F, de Vita G, Melani C, Balzi D, Sforza A, Forti G, Mannucci E, Maggi M. Male sexuality and cardiovascular risk. A cohort study in patients with erectile dysfunction. *J Sex Med* 7: 1918-1927, 2010.

- 16) Vignozzi L, Corona G, Forti G, Jannini EA, Maggi M. Clinical and therapeutic aspects of Klinefelter's syndrome: sexual function. *Mol Hum Reprod* 16: 418-424, 2010.
- 17) Comeglio P, Chavalmane AK, Fibbi B, Filippi S, Marchetta M, Marini M, Morelli A, Penna G, Vignozzi L, Vannelli GB, Adorini L, Maggi M. Human prostatic urethra expresses vitamin D receptor and responds to vitamin D receptor ligation. *J Endocrinol Invest* 33: 730-738, 2010.
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JOURNAL	IMPACT FACTOR 2015	# ARTICLE PUBLISHED
J Sex Med	2.844	84
J Endocrinol Invest	1.994	22
Andrology	2.515	17
Hum Reprod	4.621	11
Int J Androl	2.515	10
Eur Urol	14.976	10
J Clin Endocr Metab	5.531	9
Fertil Steril	4.426	8
Asian J Androl	2.644	7
PLOS One	3.057	6
Eur J Endocrinol	3.892	5
Int J Endocrinol	2.376	5

Mol Cell Endocrinol	3.859	5
J Androl	2.515	4
Best Pract Res Clin Endocrinol Metab	5.070	4
J Endocrinol	4.498	4
Nat Rev Urol	5.957	4
Prostate	3.778	4
Prostate Cancer Prostatic Dis	3.803	3
Reproduction	3.184	3
Obes Surg	3.349	3
BJU Int	4.387	3
Front Biosci (Landmark)	2.484	2
Int J Impot Res	1.396	2
Expert Opin Pharmaco	3.543	2
Expert Opin Drug Saf	2.896	2
J Reprod Immunol	3.202	2
World Mens Health	-	2
Hum Reprod Update	11.194	2
Eur J Obstet Gynecol Reprod Biol	0.808	2
Int J Clin Pract	2.226	2
Lancet Diab Endo	16.320	2
Minerva Endocrinol	1.118	2
Mol Human Repr	3.943	1
Ann NY Acad Sci	4.518	1
Sex Dev	2.164	1
Biochim Biophys Acta	5.083	1

Steroids	2.513	1
Curr Pharm Design	3.052	1
J Steroid Biochem Mol Biol	3.985	1
Expert Opin Emerg Drugs	3.058	1
Horm Mol Bio Clin Invest	0.432	1
Endocr Metab Immune Disord Drug Targets	1.987	1
Arch Esp Urol	0.307	1
Res Rep Urol	-	1
Oncol Lett	1.482	1
Curr Bladder Dysfunct	-	1
Intern Emerg Med	2.340	1
Head Neck	2.760	1
J Psychopathology	-	1
Arch Ital Urol Androl	-	1
Eur J Hum Genet	4.580	1
Curr Opin Endocrinol	3.119	1
Adv Exp Med Biol	1.953	1
J Med Genet	5.650	1
Sexual and Relational Therapy	0.714	1
Stereot Funct Neuros	1.691	1
Mol Med	3.530	1
Trends Cardiovas Med	3.075	1
Reprod Fertil Dev	2.135	1
Rev Endocr Metab Disord	5.088	1
Medicine (Baltimore)	2.133	1
J Cancer Res Clin Oncol	3.141	1

J Interpers Violence	1.579	1
Endocr Dev	-	1
Psychosom Med	3.638	1
Eur J Nutr	3.239	1
Horm Metab Res	2.029	1
Endocrine	3.279	1
Nat Rev Dis Primers	-	1
Am J Med	5.610	1
Hormones (Athens)	1.100	1
Mayo Clin Proc	5.920	1
J Urol	4.700	1