



Embryo Protection Authority Annual Report

The Embryo Protection Authority members were appointed by Hon Minister of Health Dr Godfrey Farrugia on 17th May 2013, as per Article 3 of the Embryo Protection Act enacted in December 2012. The Authority is composed of Judge Dr Philip Sciberras as Chairman, Ms Simone Attard as Vice Chairperson, and Ms Pauline Baldacchino, Ms Mariella Meachen and Dr Patrick Sammut as members. The first meeting of the Authority was held on the same day in the presence of Hon Minister.

To date 15 other Authority meetings were held.

During its initial meetings the Embryo Protection Authority invited all the stakeholders involved in the Assisted Reproduction Technology to submit their views and suggestions prior to the issuing of the Protocol / Codes of Practice. After hearing and meeting with all the stakeholders the Authority as requested by the Embryo Protection Act, held several meetings to discuss and approve such issues that will be included in the Protocol, these issues were not related only to the Medical Issues of the Couple involved but also included the Welfare of the Child to be conceived out of these IVF Procedures. In September 2013 the Authority issued the Protocol and Fertility Guidelines for Assisted Reproduction Technologies to be carried out in the Maltese Islands.

These Protocols and Fertility Guidelines were also laid on the Table of the House of the Maltese Parliament in October 2013.

The Authority has also compiled and provided all Clinics offering IVF Services in Malta with all the necessary forms required for ART procedures, these include consent of the couple to undergo treatment, consent to cryopreserve gametes and all the necessary forms for each stage of the procedure.

The Authority as established in Article 4c of the Act has carried out Inspections in one of the Private Hospitals in Malta offering IVF Services in order to ensure that the standards of best practice are being respected and implemented and that all information and documentation required under article 18 of the Act is being kept appropriately. This inspection was done co-jointly with the Licencing Authority under the Superintendence of Public Health.

The Authority constantly receives requests from Clinics to consider the attempt to fertilise three oocytes and not two for specific patients. These requests are analyzed and discussed, with the appointed consultants from the fields of obstetrics and paediatrics as per Article 6 of the Embryo Protection Act.

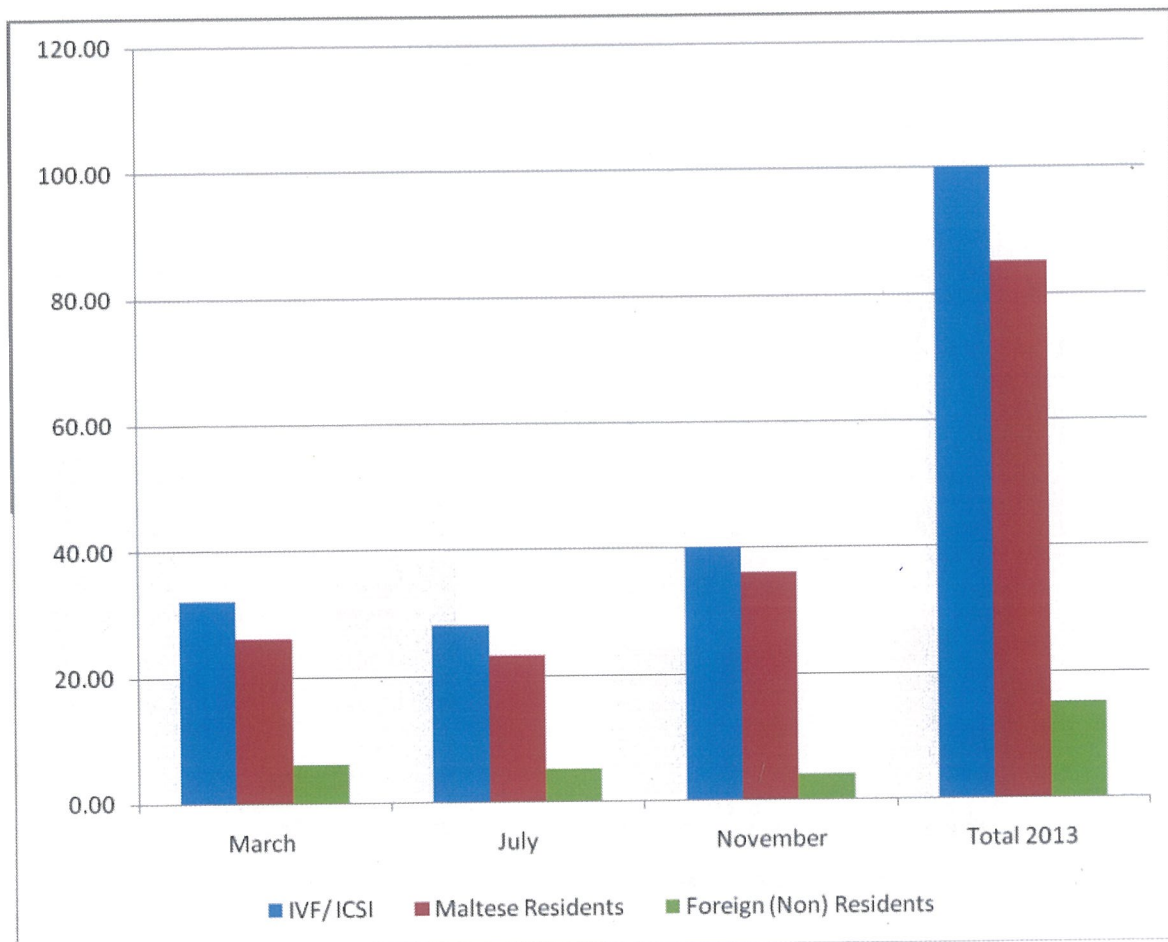
Throughout this year the Authority has also kept constant contact with all Clinics providing guidance and help where this was necessary.

The Embryo Protection Authority has for the first time in Malta (although IVF has been carried out in Malta in the private sector for several years) started to

compile the statistics related to the IVF procedures and cryopreservation of gametes.

During 2013, IVF Services were available only by the Private Sector and a total of 100 IVF / ICSI procedures were carried out spread over three sessions held in March 2013, July 2013 and November 2013.

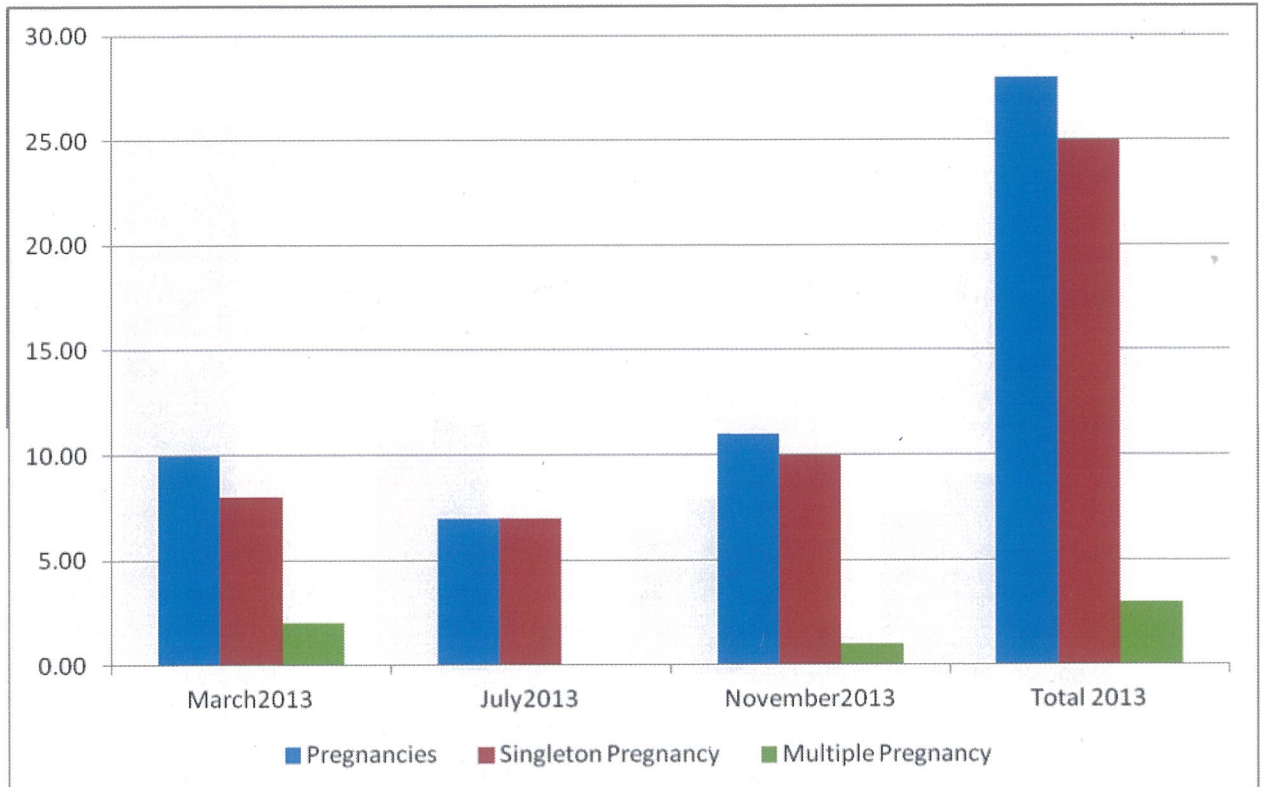
The 100 couples that underwent IVF / ICSI procedures during 2013 consisted of 85 Maltese Residents and 15 Foreigners (Non Residents) who came specifically to perform IVF in the Private Sector in Malta.



For same treatments the Authority received 23 requests for the attempt of fertilisation of three eggs for the sessions carried out in July and November 2013 respectively, out of which 14 were approved and 9 cases refused. (Please note that no previous statistics were found for requests made in March 2013, before the present Authority was appointed).

In March 2013, 32 couples underwent IVF / ICSI procedures. Out of these 10 became pregnant. Out of the 28 IVF / ICSI procedures carried out in July 2013, 7 couples become pregnant, while in November 2013 out of 40 couples undergoing treatment 11 had a successful pregnancy.

Out of these 28 Pregnancies, 25 resulted in singletons and three couples were pregnant with a multiple (twin) pregnancy.



Thus in 2013, the successful pregnancy rate was of **28%**, resulting in 25% being singletons and 3% being multiple pregnancies.

Since March 2013, the Government was constantly seeing how the IVF Services would be offered for free on the NHS from Mater Dei Hospital. To this effect an IVF Project Team was appointed to see to all the needs of that this services will require, the Authority is represented by its Vice Chairperson Ms Simone Attard on this Project Team.

The Ministry of Health also noted that patients requiring IVF cannot be put on a waiting list on a first come first serve basis, as according to the criteria established both by the NHS and also by the Authority, a maximum age limit was established, thus such patients needed priority.

To this effect the Health Ministry appointed an ART (Assisted Reproductive Technology) Prioritisation Committee with the aim to objectively rank in order of precedence the couples who are seeking assistance at the ART Clinic at Mater Dei Hospital. Priority of treatment was given to the couples where the women's age is an issue, since delays in providing an opportunity to treatment, may actually make the couple ineligible for future treatment. Other criteria taken into account were age of male partner and duration of infertility. The Authority is represented on this ART Prioritisation Committee by its Vice Chairperson Ms Simone Attard and by Dr Patrick Sammut, member of the Authority. This committee meets regularly as prioritization is needed continuously as new cases are registered each week at Mater Dei Hospital.

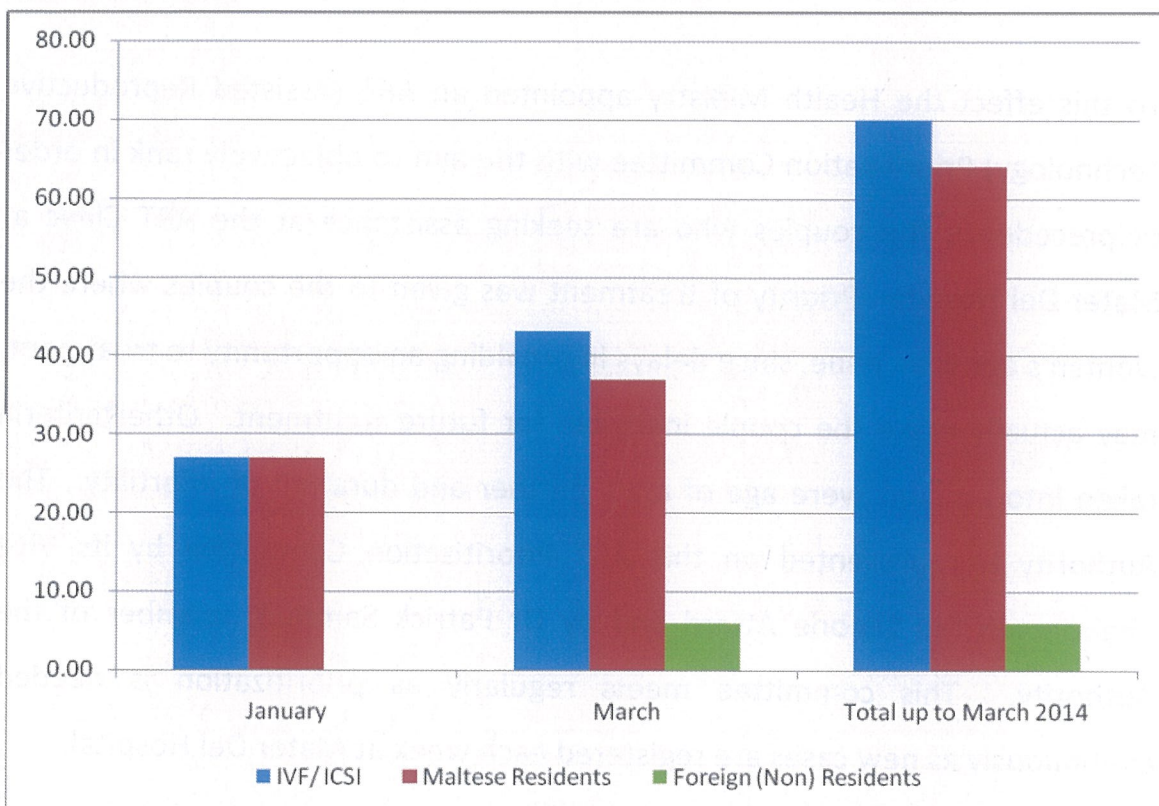
In January 2014, Mater Dei Hospital Patients started also receiving the services of IVF and a session for same was held in the early weeks of January 2014. 27 Couples underwent the IVF / ICSI procedures, all being Maltese Residents.

For these January Cycles the Authority received 15 requests for the attempt of fertilisation of three eggs which were all approved.

Out of the 27 couples undergoing IVF, 25 had successful embryo transfer out of which six couples had a pregnancy. These resulted in 6 singletons and Nil multiple pregnancies.

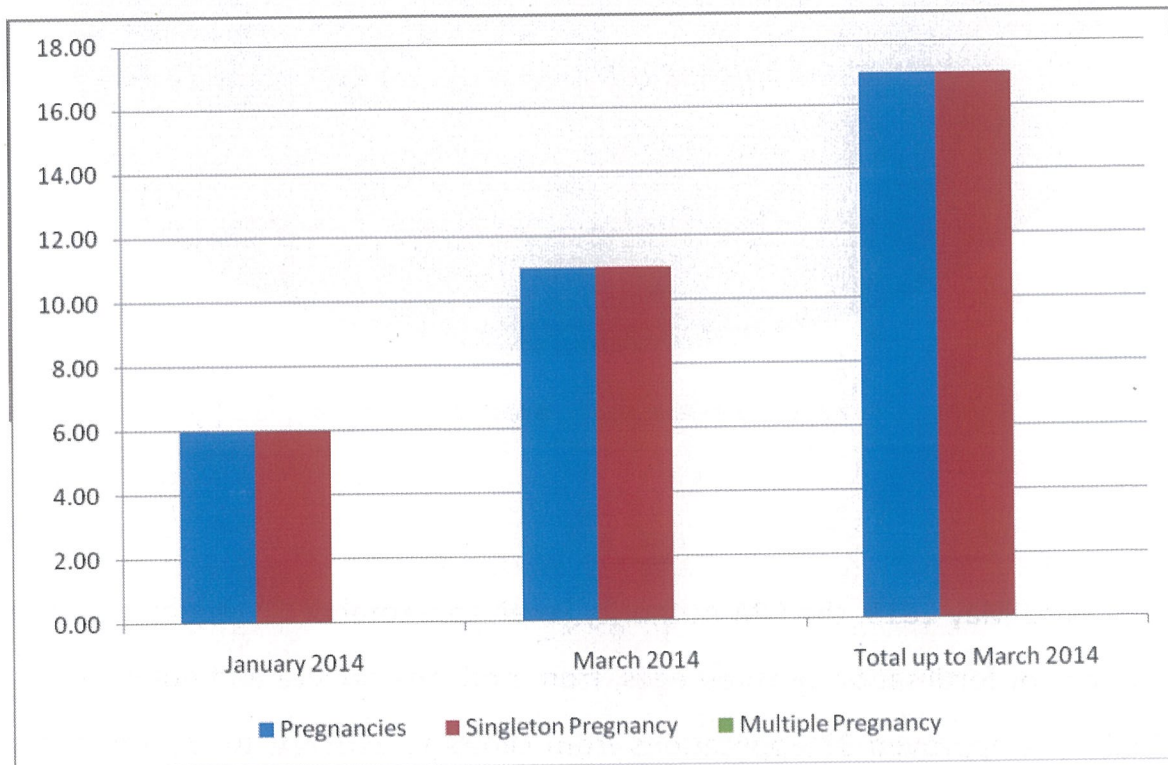
In March 2014 another cycle (largest so far) was carried out in the Private Sector with a total of 43 couples undergoing IVF.

The 43 couples undergoing IVF during this session consisted of 37 Maltese Residents and 6 Foreigners (Non Residents) who came specifically to perform IVF in the Private Sector in Malta.



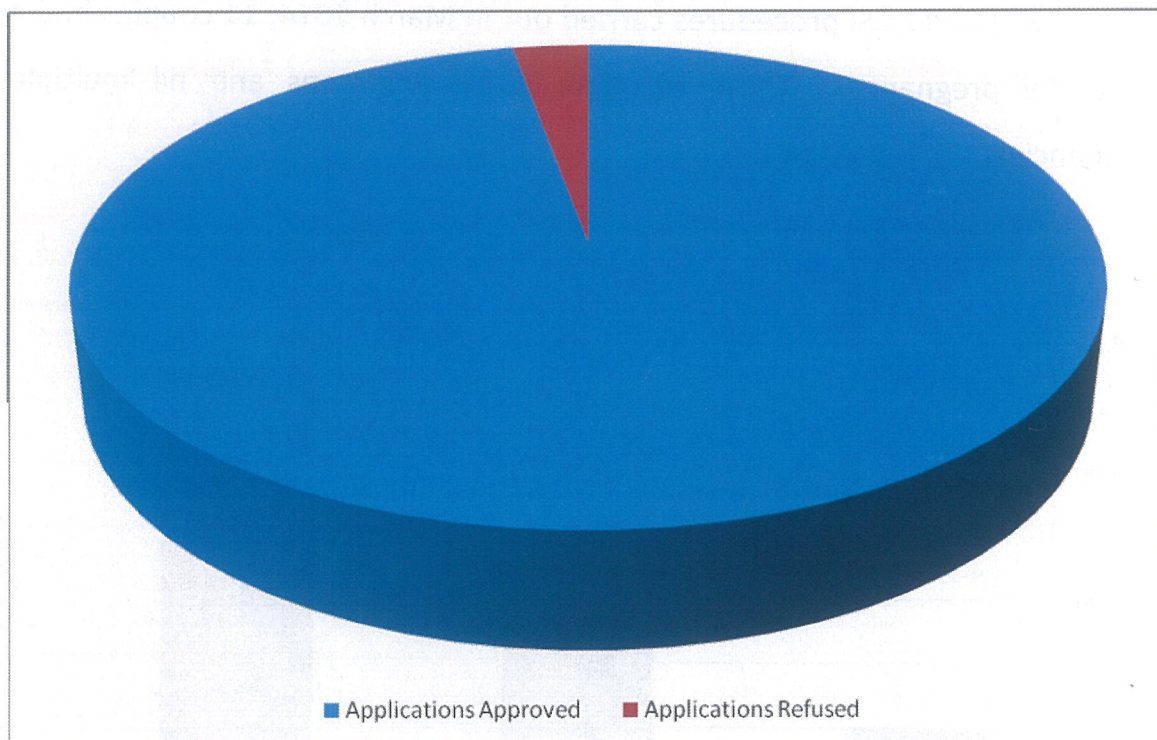
For some treatments the Authority received 14 requests for the attempt of fertilisation of three eggs, out of which 9 were approved and 5 cases refused.

Out of the 43 IVF/ICSI procedures carried out in March 2014, 11 couples had a successful pregnancy. These resulted in 11 singletons and nil multiple pregnancies.

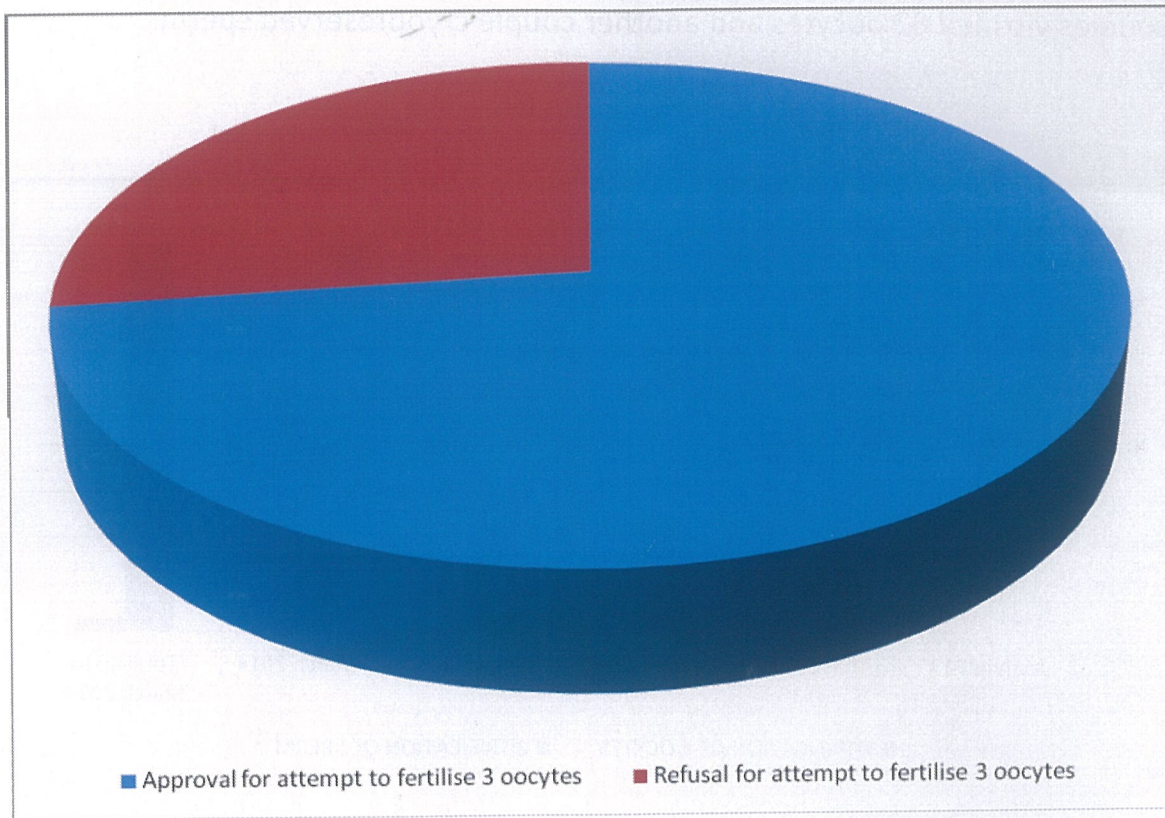


Since it was appointed in May 2013, the EPA Authority received 142 requests for IVF / ICSI procedures both in the private and public sector. It approved 138 applications from clinics to undergo IVF/ ICSI Procedures. It also declined 4 requests from Clinics to perform IVF procedures in Malta as 3 women were

over 42 years, the Maximum age as allowed by the Protocol and one woman was under the age of 25 years, the Minimum age as allowed by the Protocol.



Also since May 2013, the EPA Authority received a total of 52 requests for the attempt of fertilisation of three eggs, from both the private and public sector Clinics. It approved 38 applications from clinics to attempt to fertilize three eggs, these approvals were based on established criteria for same which include age of women undergoing the IVF treatment and previous failed cycles already undergone by the couple. It also declined 14 requests from Clinics to attempt to fertilize three eggs. These decisions were taken together with the representatives from the Obstetrics and Gynaecologists Association together with representatives from the Pediatrics Association as per required in the Embryo Protection Act.

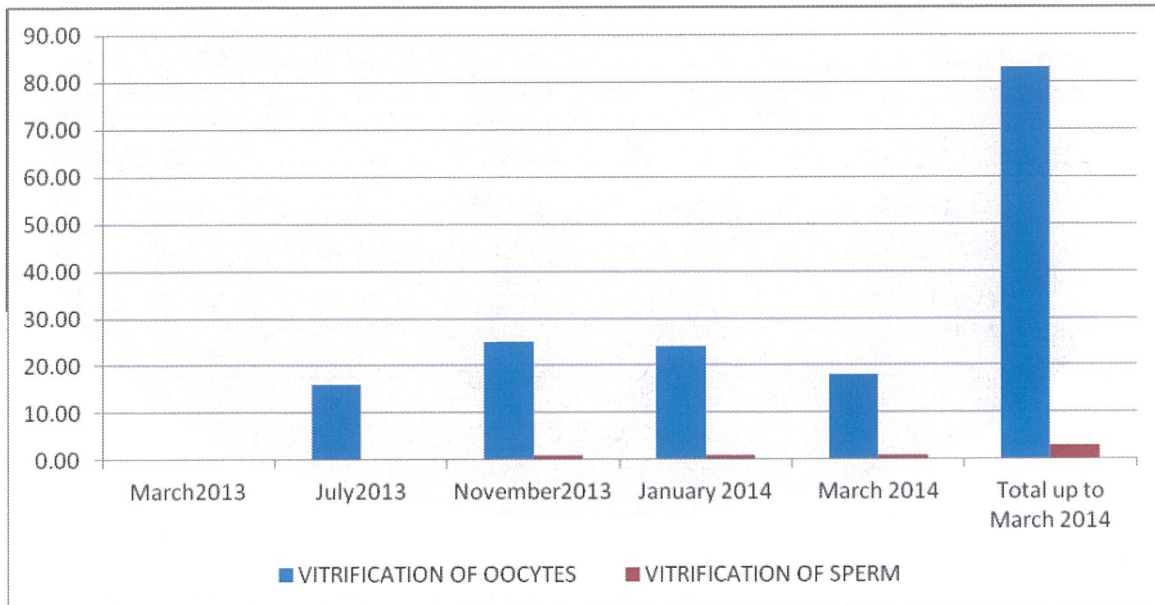


With the introduction of the Embryo Protection Act, clinics were allowed to cryopreserve / vitrify gametes. Cryopreservation of embryos is an unlawful procedure in Malta, and is allowed only in extreme cases as specified in the Act itself.

Private Clinics started to cryopreserve gametes, both oocytes (female eggs) and sperm as this procedure started taking place as from the cycles done in July 2013.

In July 2013, 16 couples vitrified oocytes totaling to 80 oocytes. In November 2013, 25 couples vitrified oocytes totaling to 84 oocytes, while another couple cryopreserved sperm. In January 2014, 24 couples vitrified a total of 92

oocytes and another couple cryopreserved sperm, while in March 2014, 18 couples vitrified 82 oocytes and another couple cryopreserved sperm.



As can be seen from all the data provided, the Embryo Protection Authority, in the last year has made a lot of work with its very limited resources. Apart from all the work listed above the Authority was continuously in collaboration with the Ministry of Energy and Health in assisting in answering the several Parliamentary Questions being made repeatedly on the Assisted Reproductive Technology procedures especially on the IVF services to be offered at Mater Dei and also on the Eligibility Criteria as established in the Embryo Protection Authority's Protocol.

Moreover the Authority was also giving guidance both to the existing clinics offering the IVF service in the private sector and also to the new service provider who will now offer the services from Mater Dei Hospital.

To date the Authority still operates from a small room within St Luke's Hospital with no premises yet assigned to it. In the coming month we will be moving to a larger room within the Entitlement section of St Luke's Hospital but still this is not enough for the Authority to operate and perform all of its functions as prescribed in the Embryo Protection Act. Also to date the Authority is still without any Human Resources and all the above work have been done strictly by the members of the Board of the Authority, together with the Board's secretary.

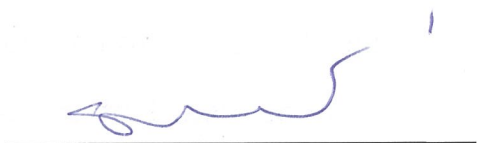
The Embryo Protection Authority recommends that the Legal Notice Proposed by the Authority to add new provisions to the Embryo Protection Act, will become in force as soon as possible. This Legal Notice is in line with the Government's Manifesto proposal to ensure that the IVF Authority will have all the necessary resources. The need of adding new provisions to the Act is two-fold:- (1) to provide EPA with the necessary tools for its operations, and (2) to bring it in conformity with other statutory Acts establishing the setting up of the different Authorities.

We look forward that the Governing Authorities see to the Embryo Protection Authority's request, so all of the functions of the Authority as set out in the Embryo Protection Act can be fully met.



Judge Dr Philip Sciberras LLD

Chairman



Ms Simone Attard PGrad Cert, PGrad Dip, Family Therapy (Tavistock London and Portman NHS Trust), MBICA

Vice Chairperson

30th May 2014