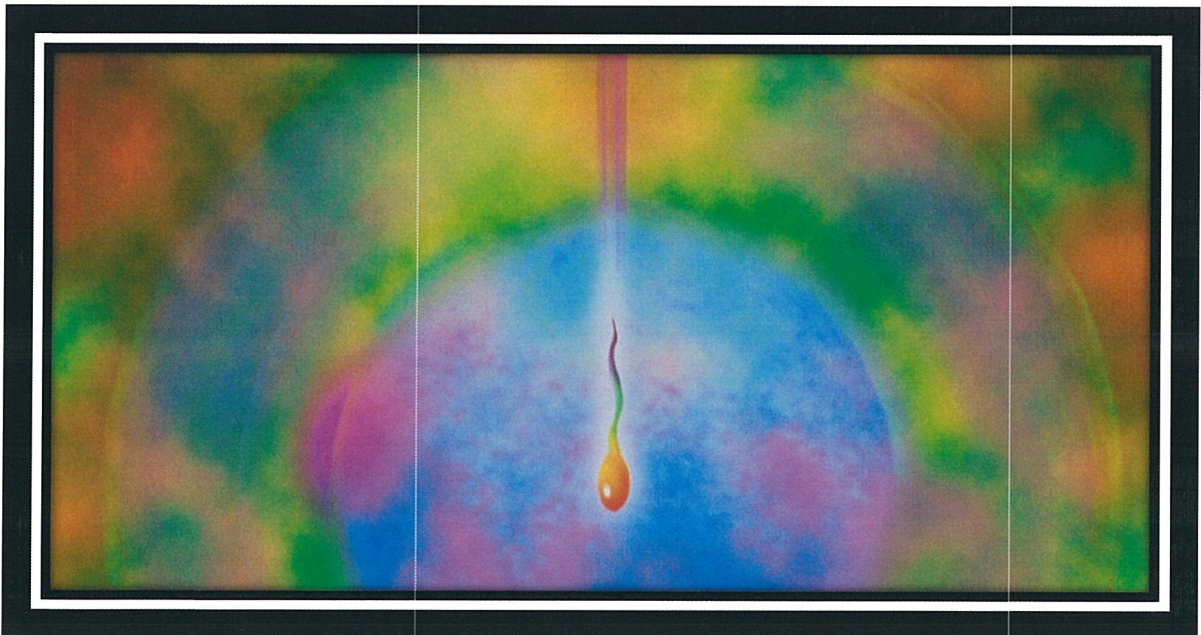


EMBRYO PROTECTION AUTHORITY

PUTTING PATIENTS FIRST

TRENDS AND FIGURES OF FERTILITY TREATMENTS IN MALTA FOR 2014

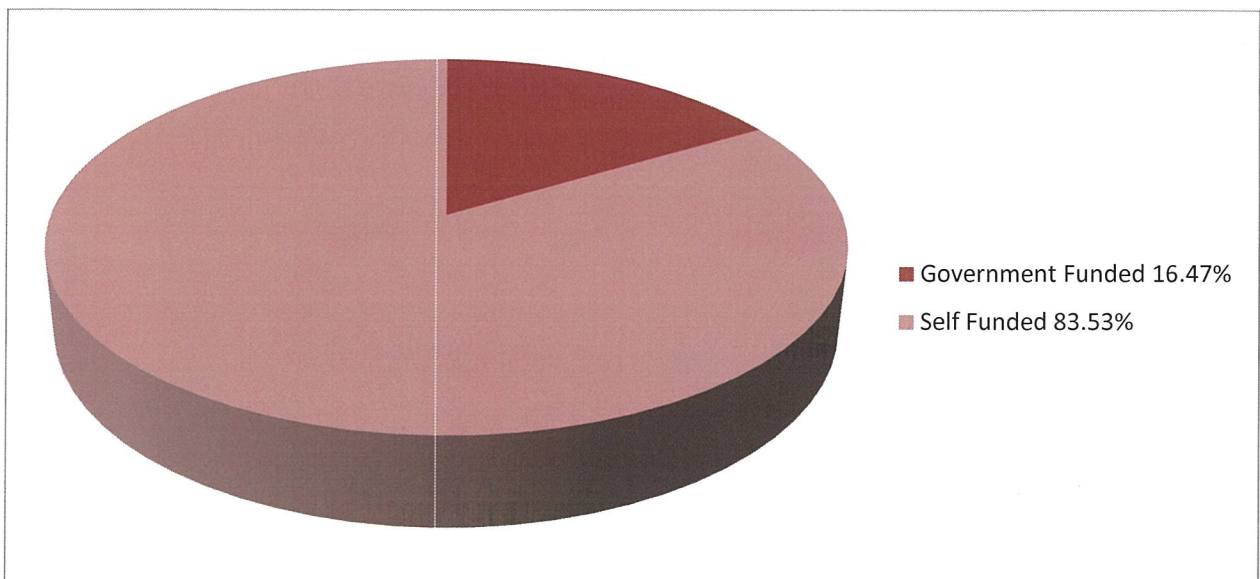


Cycles Performed

During 2014, the Authority received 170 applications from Clinics both in the Private and Public Sector, All 170 applications were approved by the Board, thus 170 cycles of IVF / ICSI were carried out in Malta by the licenced Centres both Public and Private. These cycles were spread and performed in 4 periods, namely January, March, July and November.

For the first time in Malta in January 2014, the Government started to pay for cycles being carried out free of charge to patients through the Artificial Reproductive Clinic at Mater Dei Hospital.

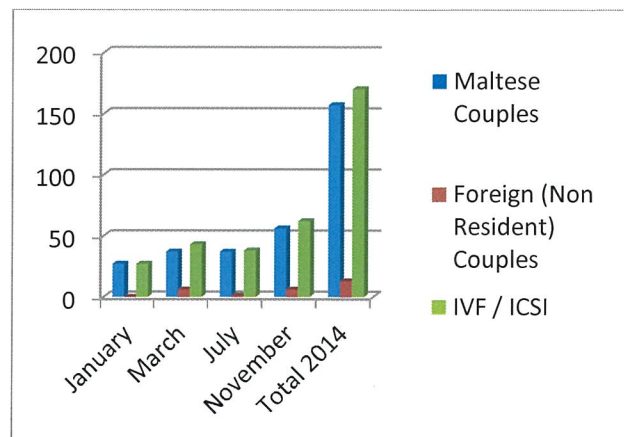
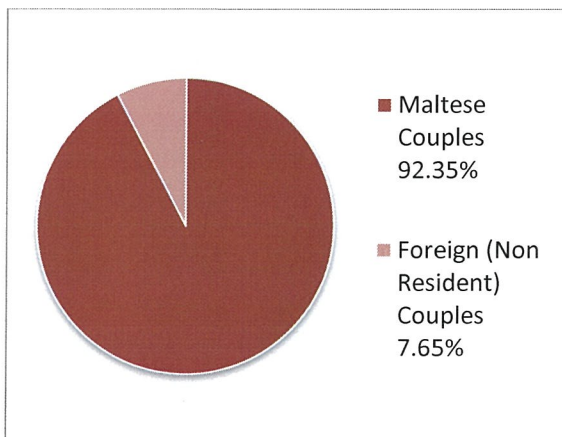
During this year, 28 couples received government funded cycles, while the other 142 cycles were self funded by patients.



This trend of Government Funded cycles will continue to Increase as the ART Clinic at the Public Hospital Mater Dei has from January 2015 started to offer its free services every 8 weeks.

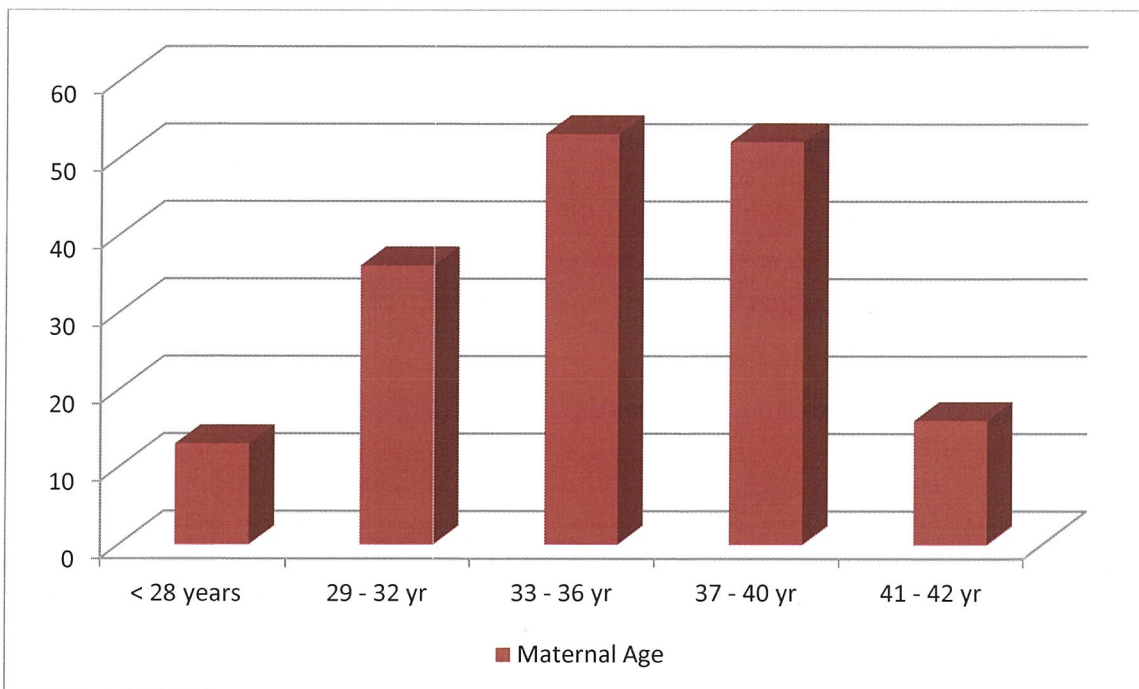
Maltese / Foreign Patients

The 170 couples that underwent IVF / ICSI procedures during 2014 in Malta consisted of 157 Maltese Residents and only 15 Foreign (Non Residents) couples who came specifically to perform IVF in the Private Sector in Malta. This shows a considerably decrease from the previous year as in 2013 there were 15% of the couples that were foreigners while during 2014 only 7.65% of couples are foreigners seeking treatment in the Private Sector, this decrease could also result from the current situation in the countries surrounding the Mediterranean, mainly Libya with patients not being able to come for treatment to Malta.



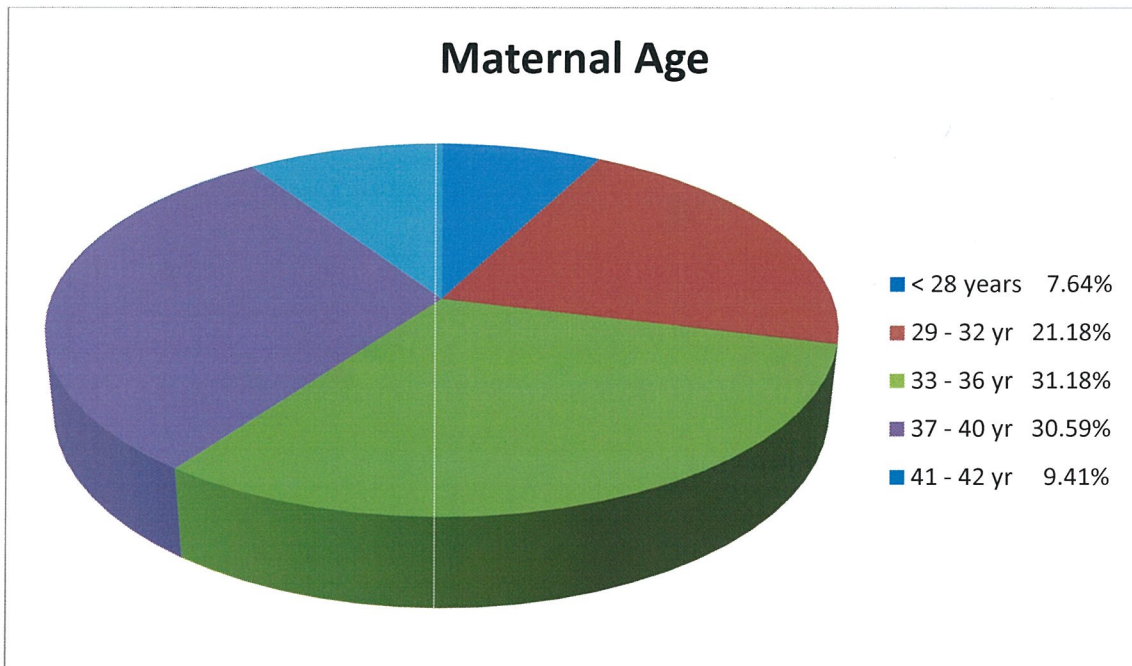
Maternal Age

In Malta all IVF's / ICSI's are to be carried out within a Maternal Age stipulated bracket, with the limit being between minimum 25 years and maximum 42 years. During 2014 there was a distribution of procedures carried out in all age brackets as can be seen from the hereunder chart.



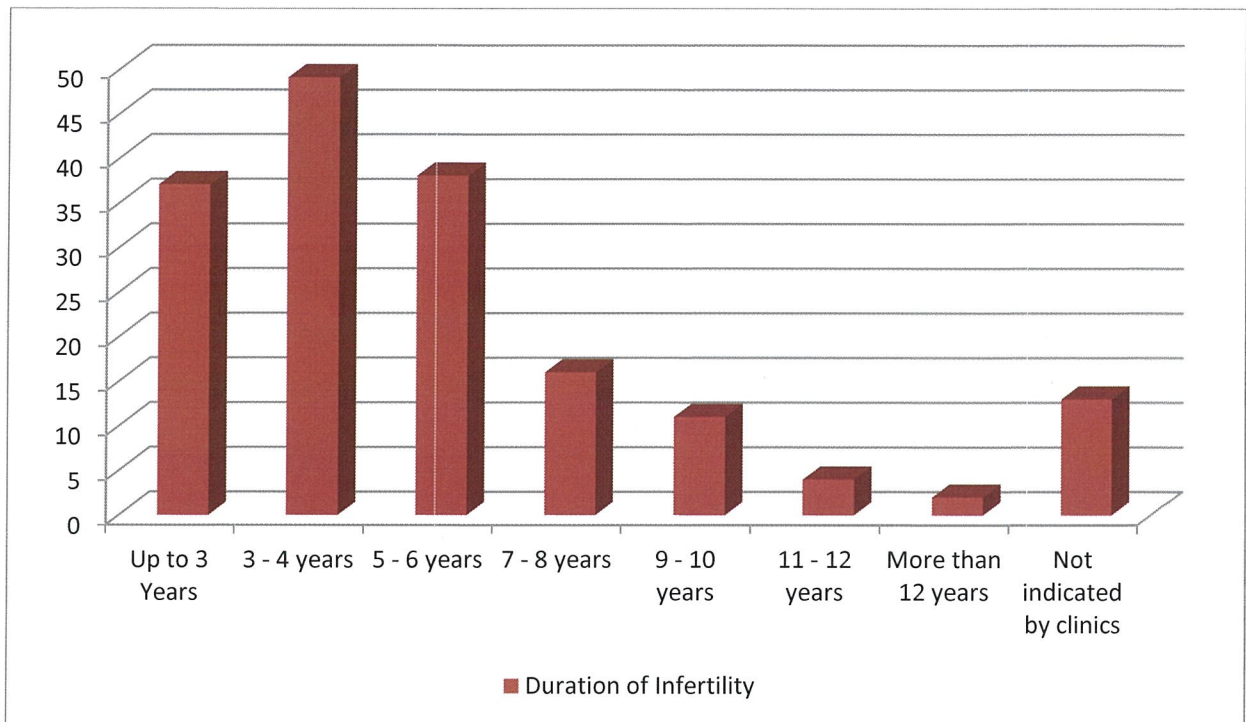
It is noted that the most age group referred for IVF is that were the woman is aged between 33 - 36 years of age, followed closely by the age group were the woman is 37 - 40 years of age, the age trend then follows with woman between 29 -32 years whilst as expected woman between 41 – 42 years of age place 4th.

The lowest number of couples referred for IVF come from the youngest age group that where the woman is aged under 28 years, this is also in line with international figures where the couple wait to have further investigations and other ART Procedures prior to resorting to IVF / ICSI.



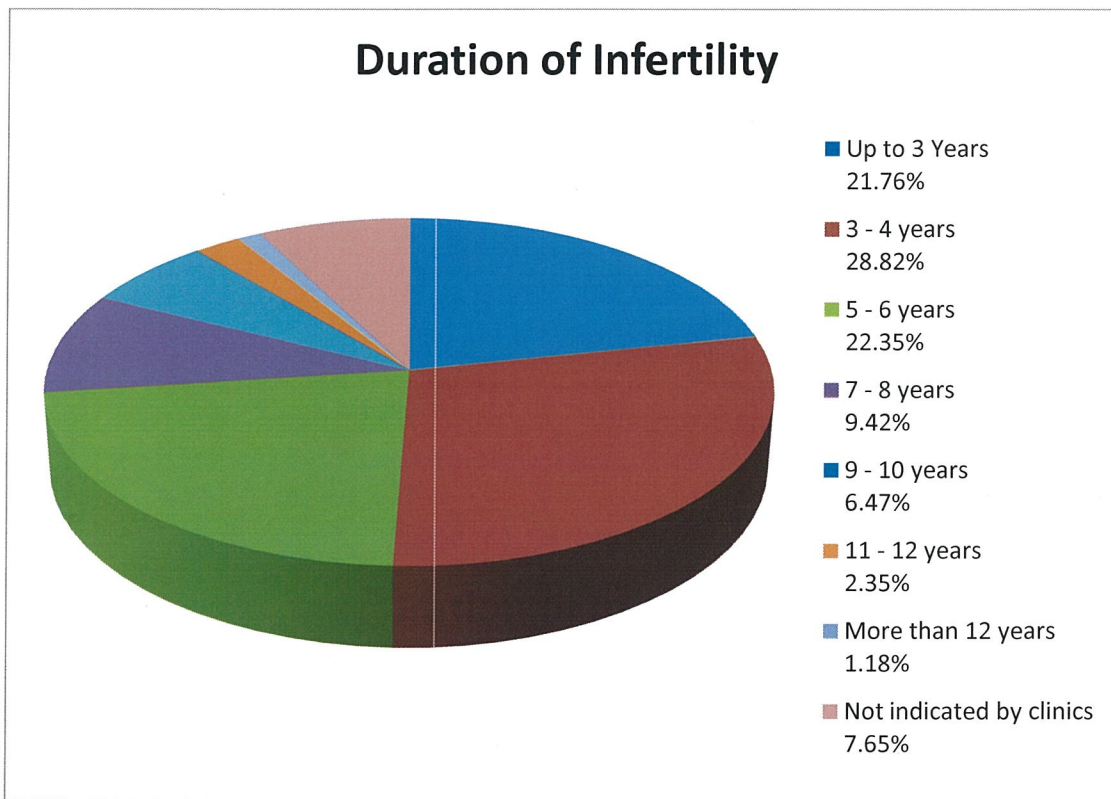
Duration of Infertility

From the statistics that the Embryo Protection Authority collects from the Licenced clinics, it has been noted that there is a big variance in the length of the duration of the period that the couples are trying to conceive (duration of infertility) prior to seeking help though IVF and ICSI.



The most couples referred for IVF are those that have been trying to conceive between 3 - 4 years, this is followed by couples that are in the 5 - 6 years duration of infertility group. This data shows how couples seek other infertility treatment options such as medication / Artificial Inseminations and Intrauterine Insemination prior to moving on with ICSI / IVF.

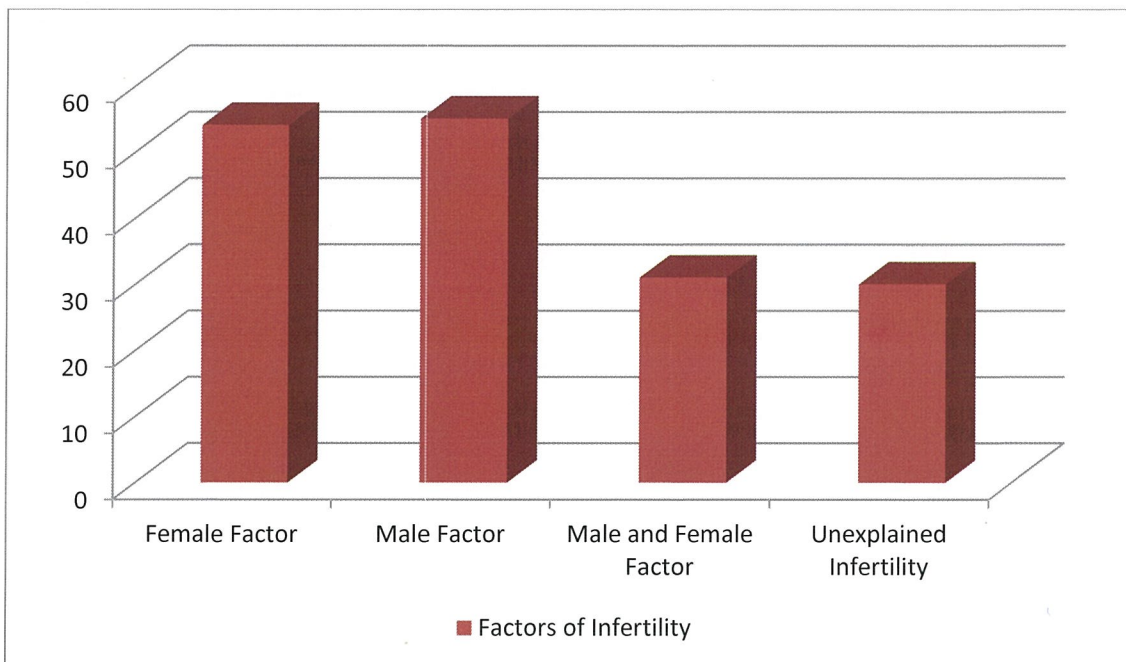
However it is good to note that there were quite a considerable number of couple that were undergoing IVF for the first time with over 7 years infertility with the number of couples still high up to 10 years of Infertility. There were also 6 cases that were reported that they were undergoing IVF for the first time with an infertility duration of more than 11 years. One of these couples had been trying to conceive for 14 years while another couple even reported an Infertility duration of 19 years.



The attributing factor in the prolonged duration of Infertility was seen due to the fact that for the first time in Malta IVF was being offered for free on the National Health Scheme, so couples that never afforded financially to do IVF / ICSI in the private sector or abroad, were now being offered the service by the Government at the State Public Hospital Mater Dei and they took the opportunity to go for Artificial Reproductive Technology for the first time in their relationship.

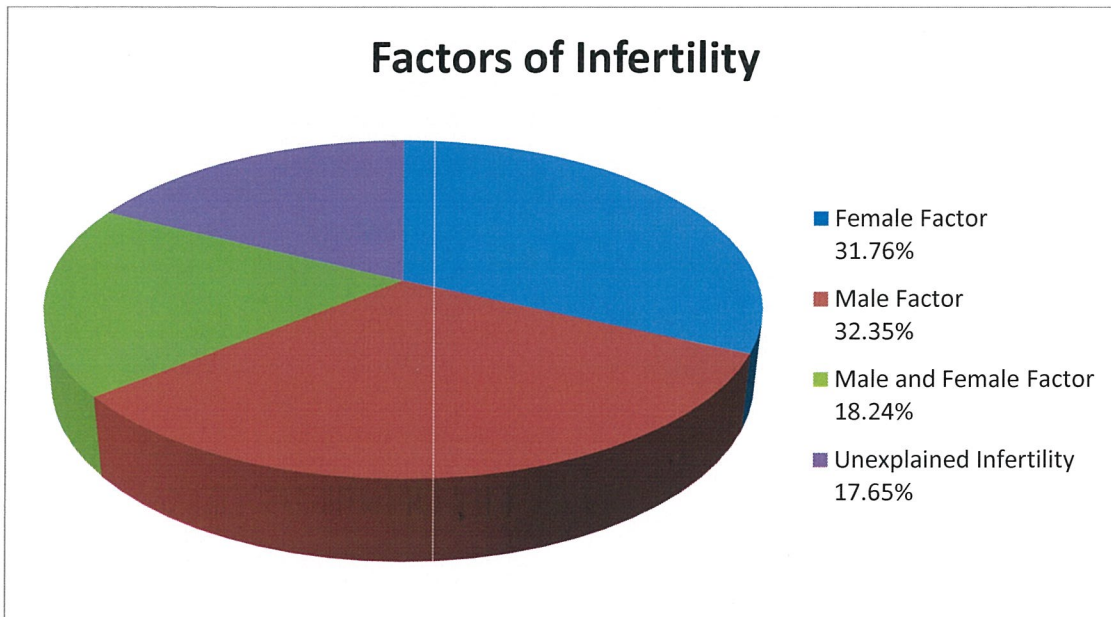
Factors of Infertility

The couples undergoing fertility treatment in Malta were also asked to report what is their main infertility factor. This information requested by the Embryo Protection Authority from the Licenced Clinics was split into Four different categories, namely: Solely Female Factor Infertility, Solely Male Factor Infertility, Both Male and Female Infertility and Unexplained Infertility.



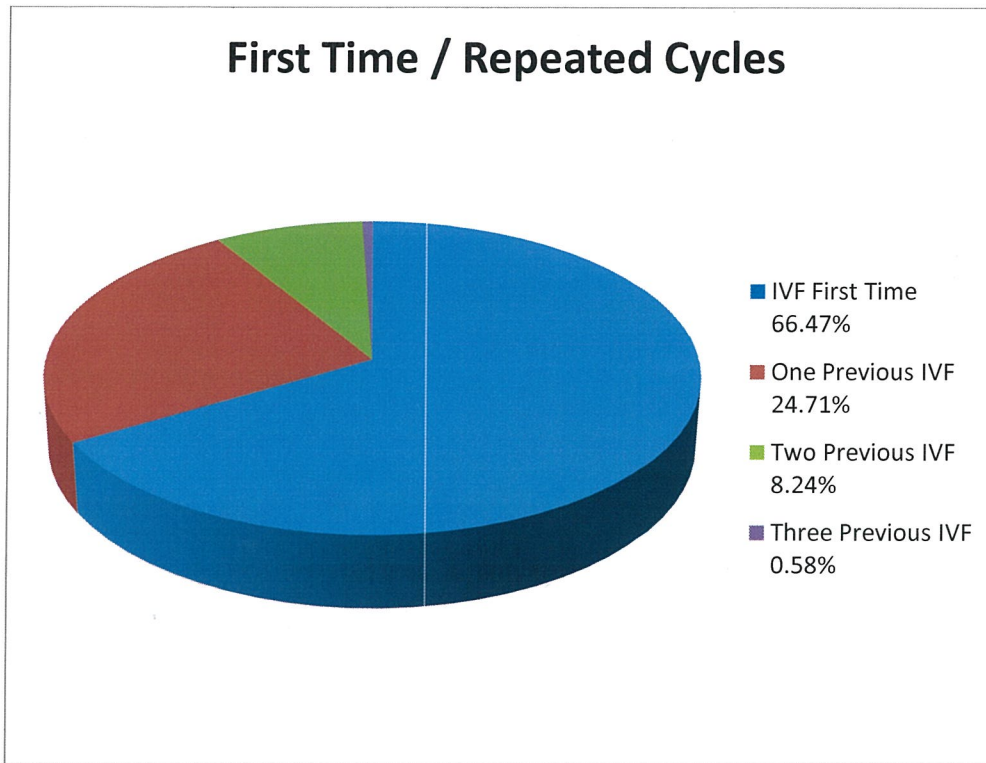
The highest percentage of couples seeking Artificial Reproductive Technologies of IVF and ICSI in Malta have a Male factor Infertility with a 32.35% of the couples, these are followed by Female factor Infertility with 31.76%. It is also of importance to note that 18.24% of the couples that have resorted to IVF had both Male and Female Factor Infertility, whilst 17.65% of the patients were identified with Unexplained Infertility, which is defined as no medical reason

for Infertility but the couple still do not conceive after years of trying to have a child.



First Time / Repeated Cycles

Out of the 170 cycles carried out in 2014, the Majority of the couples 66.47% were undergoing their IVF / ICSI for the first time, whilst other couples were repeating their IVF cycle which they had already undergone previously either locally or abroad, the number of previous cycles range from one to three previous cycles.

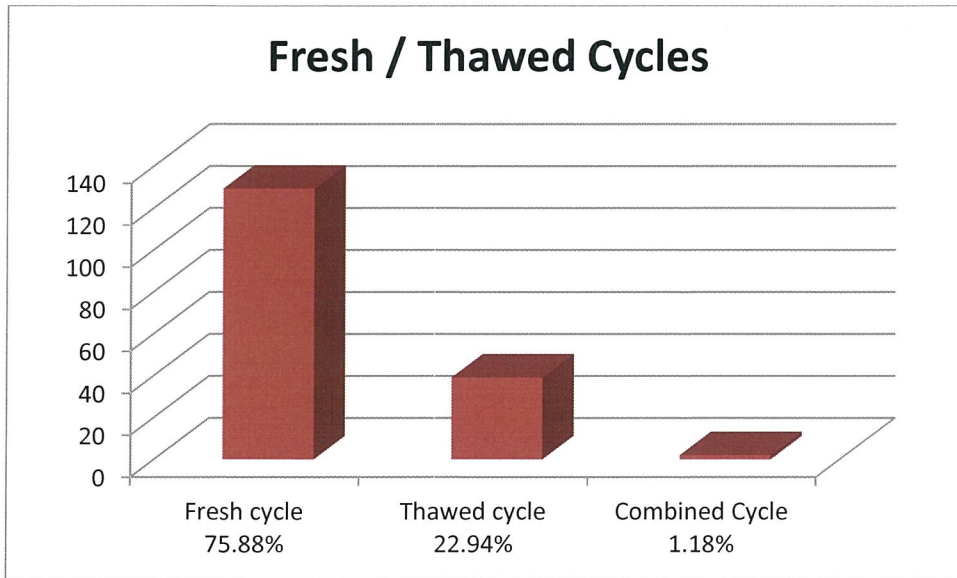


Fresh / Thawed Cycles

With the Introduction of the Embryo Protection Act in 2013, the licenced centres are also permitted to cryopreserve gametes, both oocytes and sperm, thus allowing the couples to make use of cycles that use only thawed oocytes or a combination of thawed and fresh oocytes.

The compiling of this data is very important, due to the fact that Malta is one of the very few countries that are only permitted to do oocytes and sperm freezing and does not permit embryo freezing. This data will provide the Authority with very useful information whether Malta can get successful pregnancy rates from

cycles using thawed gametes and compare these with successful pregnancy rates from fresh gametes.



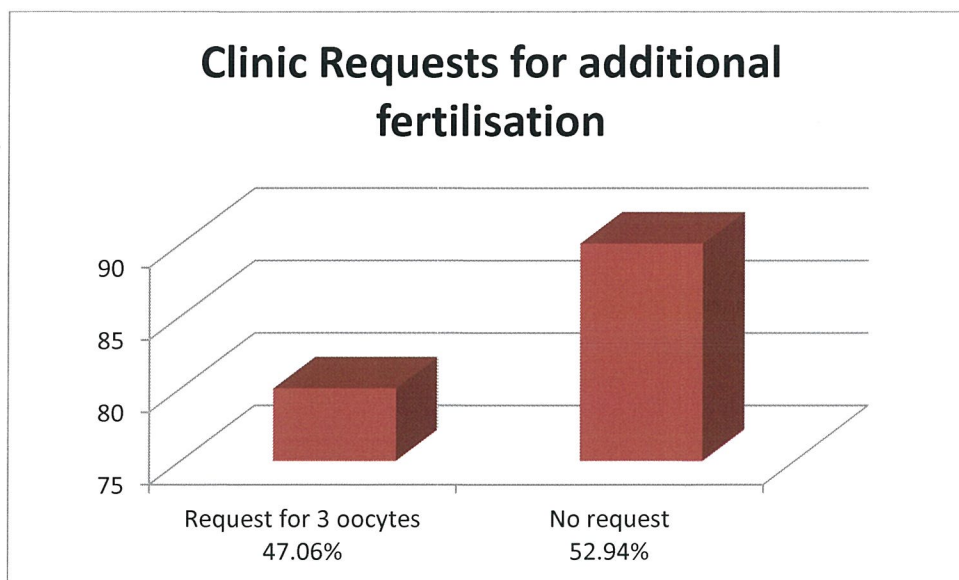
In 2014, out of the 170 cycles carried out the total majority 129 cycles - 75.88% were from fresh gametes while 39 cycles - 22.94% used thawed gametes. Only two cycles, that is 1.18% made use of a combined cycle using fresh and cryopreserved oocytes together.

Couples making use of fresh cycles or solely thawed cycles were spread over the full range of women's age range of 25 – 42 years. The two couples making use of the combined cycles, were couples with the woman aged between 37 – 40 years of age.

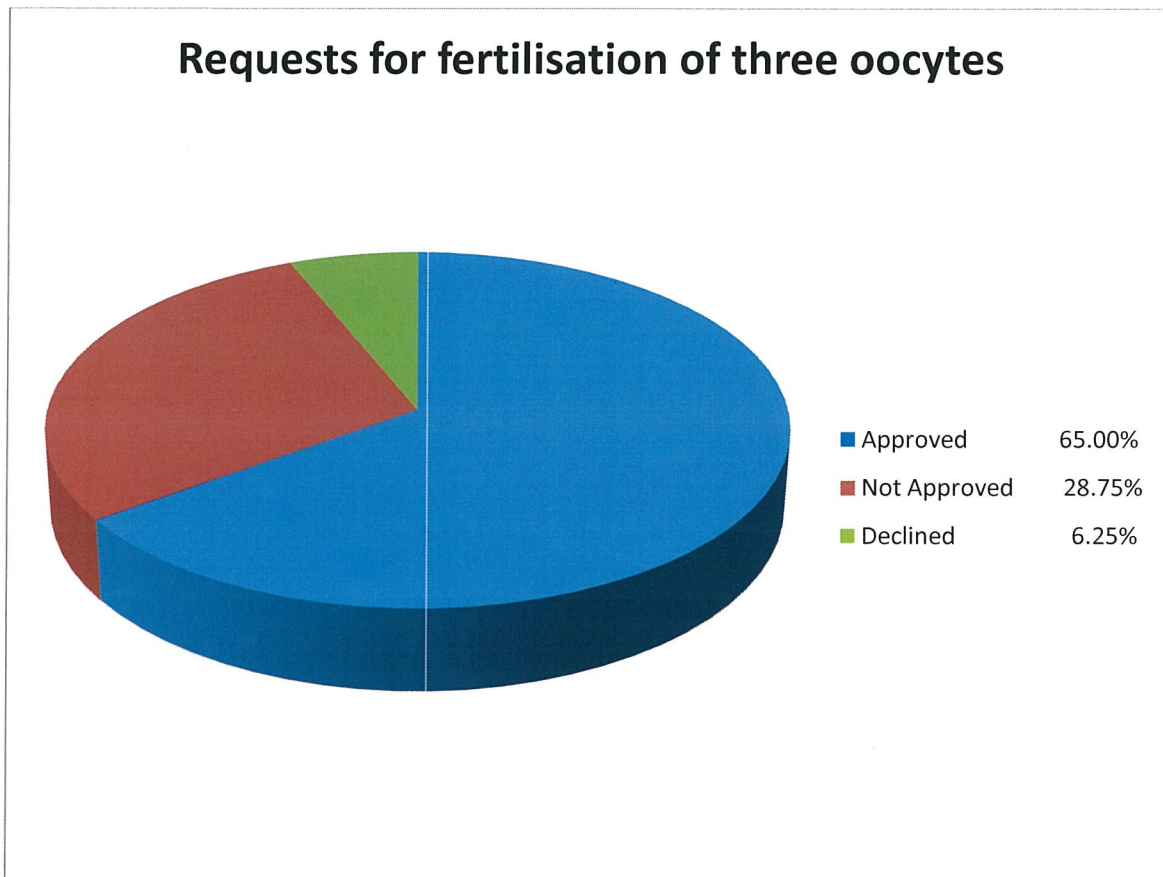
Requests for the fertilisation of three oocytes

The Authority constantly receives requests from both the private and public sector Clinics to consider the attempt to fertilise three oocytes and not two as allowed by the EPA Act for specific patients. These requests are analyzed and discussed by the Board together with the appointed consultants from the fields of obstetrics and paediatrics as per Article 6 of the Embryo Protection Act. These cases are considered on already established criteria which include age of women undergoing the IVF treatment and previous failed cycles already undergone by the couple.

Clinics only made Additional Fertilisation requests for 80 cycles out of the 170 cycles carried out, thus requests were made only for 47.06% of the total cycles while 52.94% of the cycles were decided by the clinicians and couples to be carried out with two oocytes as allowed by Law.



The Board together with the representatives assessed the requests for the fertilisation of three oocytes as per the established criteria and out of the 80 requests approved 52 cases - 65%, 23 cases - 28.75% were not approved as they did not meet the established criteria, while another 5 cases – 6.25% were declined due to the late submission of the cases by the respective Clinics, thus their cases were not considered by the Board for the fertilisation of three oocytes, thus cycle will be carried out as per allowed by Law, that is two oocytes only. In the latter 5 cases apart from informing the clinics about this decision, couples were also sent a letter explaining the late submission of the clinic, thus the non-compliance with the Authority's Protocol.



Cryopreservation of gametes

Private Clinics in Malta started to cryopreserve gametes, both oocytes (female eggs) and sperm as from the cycles done in July 2013. Government funded cycles also started to make use of cryopreservation as from January 2014.

During 2014, 87 couples made use of the cryopreservation of oocytes while 3 couples made use of sperm freezing.

Out of the 90 couples that cryopreserved gametes, 7 couples cryopreserved their gametes for future use only and did not include an IVF / ICSI cycle together with the cryopreservation. These were granted permission from the Authority and included 3 couples that cryopreserved sperm only while 4 other couples cryopreserved oocytes only for future use.

Cycles Started

Although this report is based on 170 cycles that have been performed in Malta, the Clinics also reported that there were 5 other couples that had started to take medication but had to abandon the cycle prior to egg retrieval as the woman's ovaries did not respond well or had a poor response to the stimulation treatment, so the couple were advised not to go for the IVF / ICSI procedure.

Another cycle was reported to be abandoned before stimulation phase started as the foreign patient was diagnosed as Hepatitis Positive and thus was advised to continue treatment abroad in a specialised licenced centre.

Embryo Transfers

Out of the 170 IVF cycles carried out in 2014 in Malta, not all 170 had embryo transfers. In fact only 159 cycles (93.53%) had viable embryo transfers, while 11 cycles (6.47%) did not have an embryo transfer.

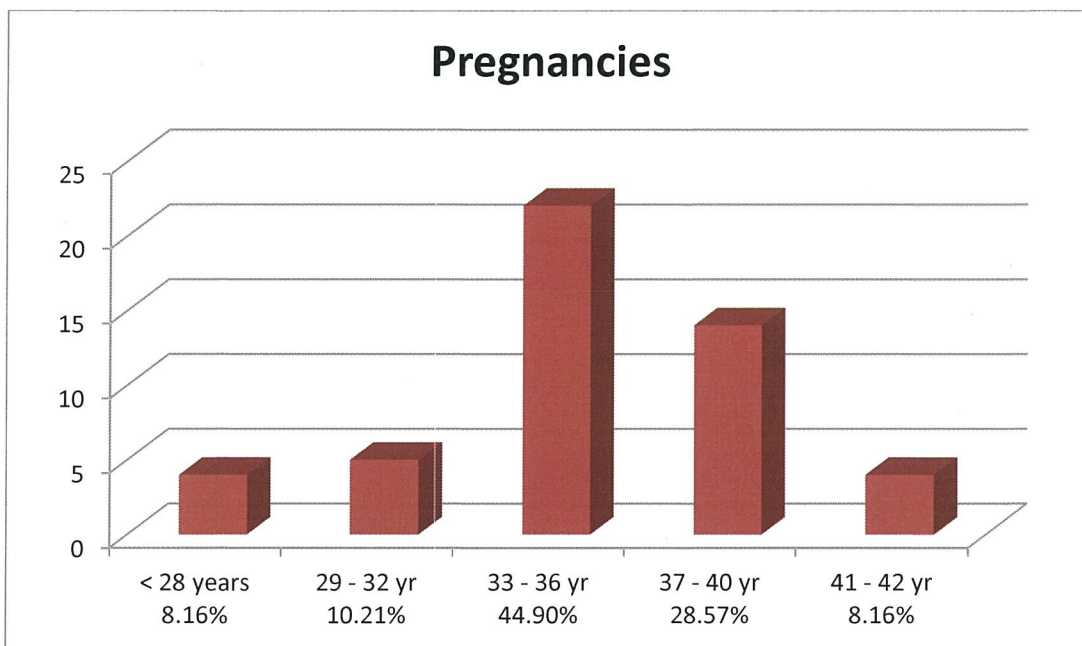
The reasons for not having embryo transfer can be various, one reason would be that while the eggs were being retrieved the Male partner was not able to produce a sample so the eggs would be frozen for later use and no IVF performed. Another reason is that the eggs retrieved would have been of a poor quality and were not good to undergo the IVF procedure so would be discarded, One other reason is that although fertilisation would have taken place, the embryo does not develop to be transferred back.

A reason for a cycle to fail between egg retrieval and fertilisation thus resulting in no embryo transfer is where a risk of OHSS (Over hyper stimulation) was identified. It is very important to note that a risk of OHSS is not the same as a diagnosis of OHSS and identifying this can be a safe part of the clinical management of the woman's health, thus the clinician would go for a decision to freeze all oocytes instead of continuing with the fertilisation of the oocytes. This would also result as a no Embryo transfer cycle.

During 2014 there were no requests from Clinicians / Responsible Persons of Licenced Clinics for the cryopreservation of embryos. In Malta cryopreservation of embryos can only be granted by the Embryo Protection Authority as per Article 7 of the Law, where the transfer of the fertilized embryos into the womb is not possible owing to grave and certified *force majeure* not predictable at the moment of fertilization.

Results – Pregnancies

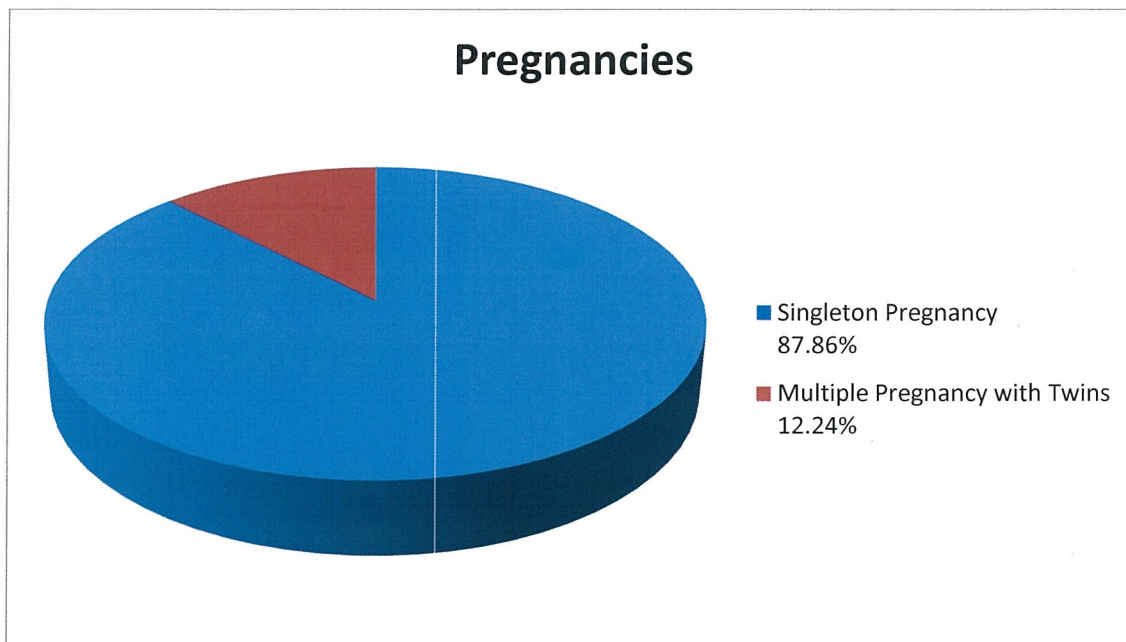
The pregnancies achieved from the cycles carried out in 2014 resulted in 49 pregnancies out of the 170 cycles carried out. This gives us a **28.82%** of successful pregnancies out of all the cycles started and a successful pregnancy rate of **30.82%** of the total of embryo transfers made.



Pregnancies reported were in all age groups with the highest pregnancy rates reported in the age group where the woman is aged 33 - 36 years, this is followed by the age group where the woman is aged 37 – 40 years. The lowest pregnancy rates achieved were in the youngest and oldest age groups respectively.

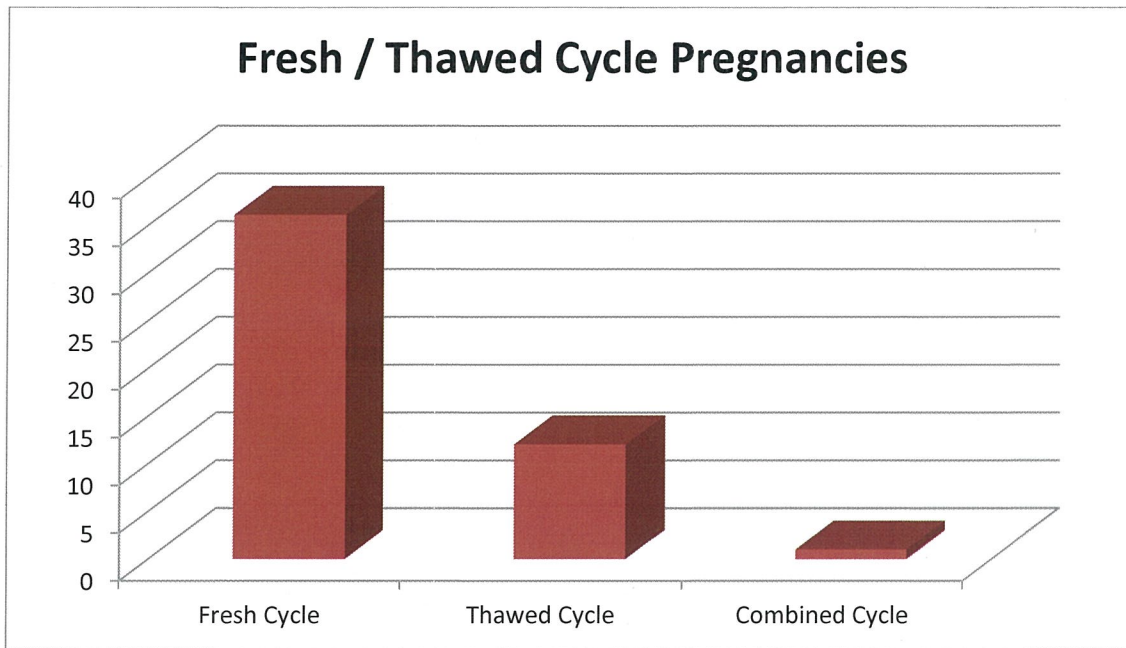
Single / Multiple Pregnancies

The 49 pregnancies reported in 2014 resulted in 43 pregnancies in singletons and 6 pregnancies with multiples. A multiple pregnancy is a pregnancy where two or more embryos develop at one time in the womb. The six multiple pregnancies reported in 2014 were all twin pregnancies. There were no pregnancies reported with triplets from IVF / ICSI Procedures.



Fresh / Thawed cycle Pregnancies

Out of the 49 pregnancies there were 36 pregnancies from 129 fresh IVF cycles, while 12 pregnancies were reported from 39 thawed cycles and one pregnancy from the 2 combined cycles using fresh and thawed oocytes.



When one analysis the percentage successful rate for each category, the thawed cycles had a **30.77%** success rate while the fresh cycles had a **27.91%** success rate.

Considering the fact discussed earlier, this is a very encouraging percentage achieved by the thawed cycle procedures as in proportion the cycles carried out with thawed oocytes were more successful.

Three Oocytes Requests - Pregnancies

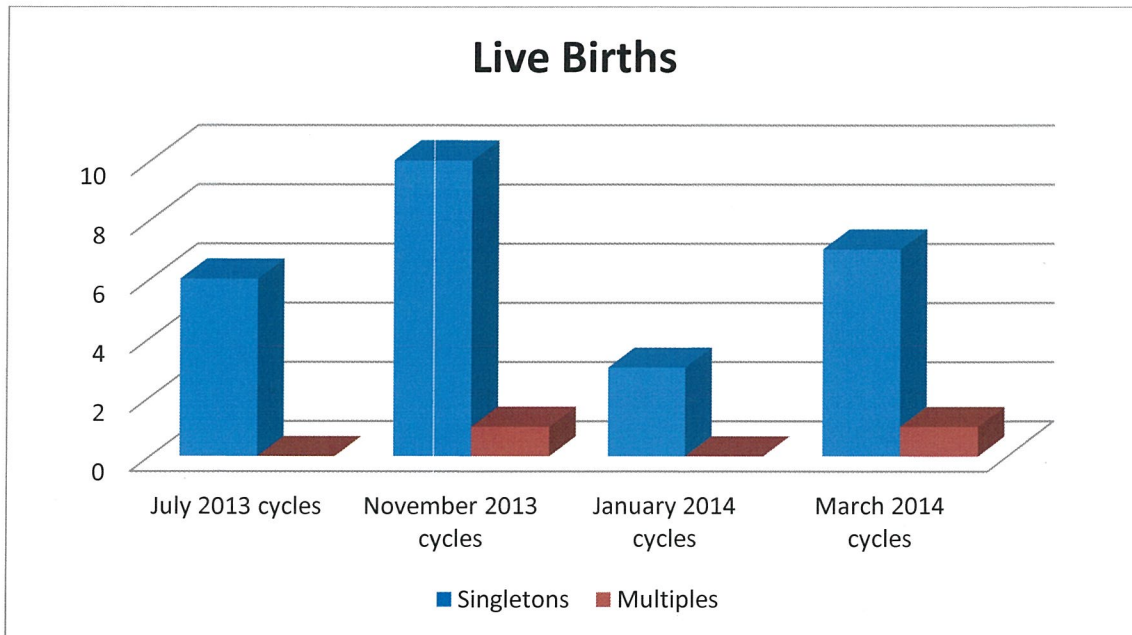
Out of the 49 pregnancies reported in 2014, 34.69%, 17 cases had the approval for the fertilisation of three oocytes, 10.20% of the pregnancies, 5 in No did not have approval, while 53.06% did not have any request for the additional fertilisation. Only one couple from those applications that were declined became pregnant.

Live Births

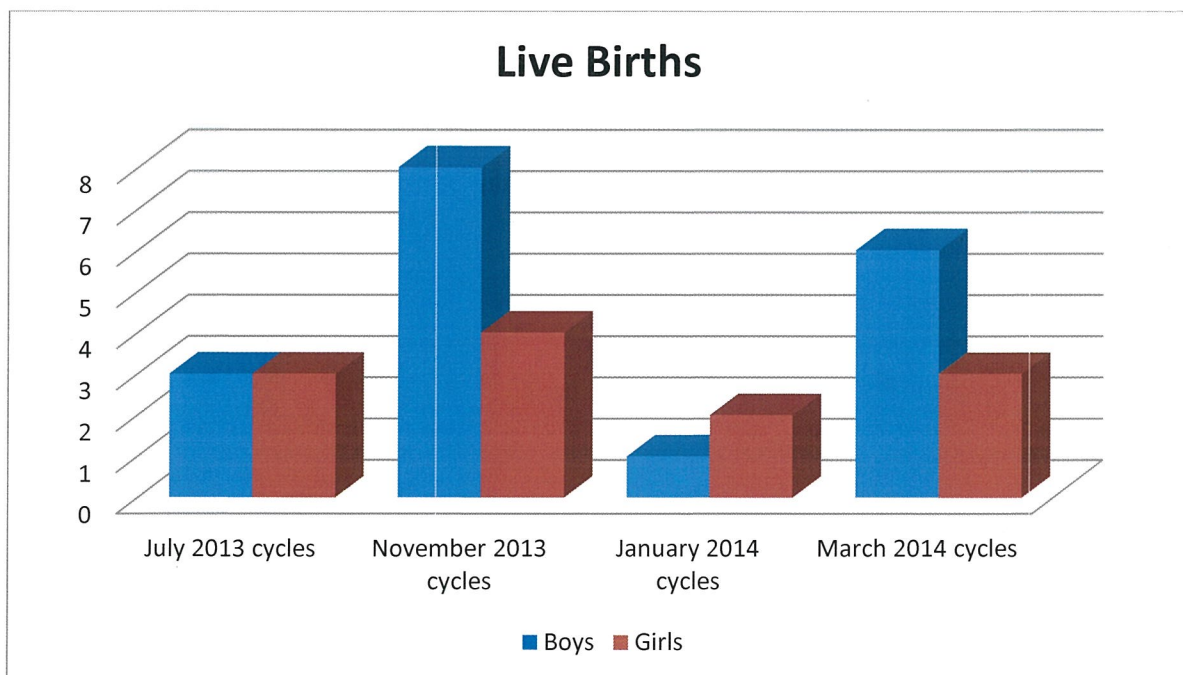
In 2014 live births from IVF cycles carried out in July 2013, November 2013, January 2014 and March 2014 were recorded born both at the Public Hospital and also at Private hospitals.

18 babies were born as a result of cycles carried out in July and November 2013, while 12 babies were born as a result of IVF cycles carried out in January and March 2014.

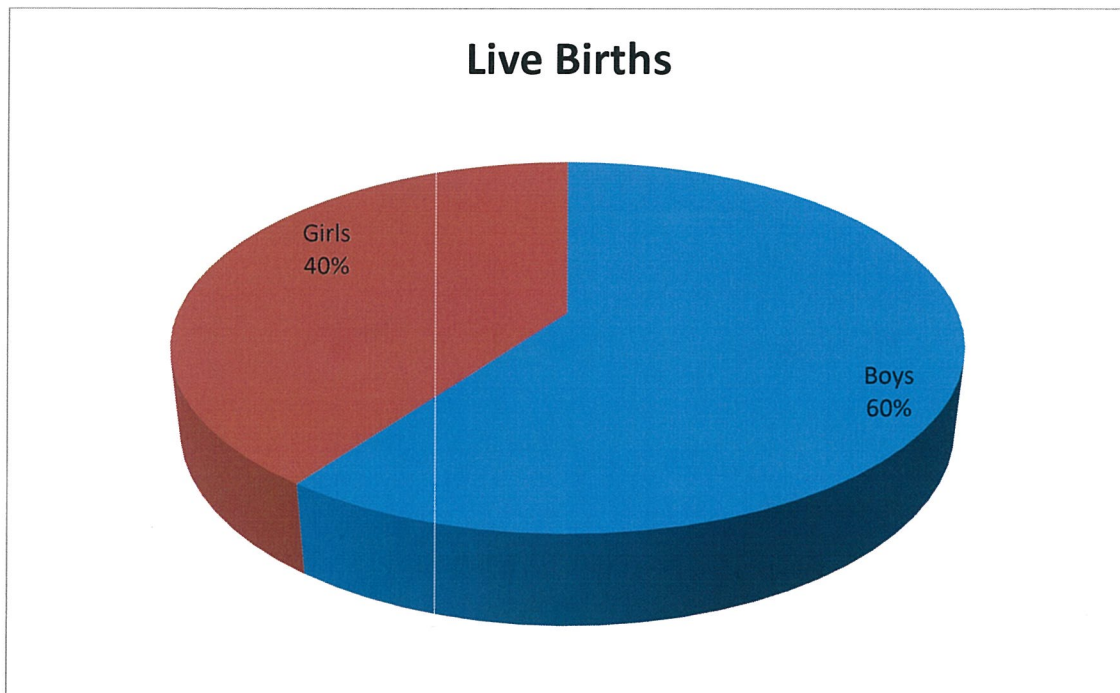
These 30 newborn babies were born from 28 pregnancies thus being 26 singleton pregnancies and two multiple (twin) pregnancies.



From the July 2013 cycles 6 babies were born consisting of 3 boys and 3 girls, out of the November 2013 cycle, 12 babies were born consisting of 8 boys and 4 girls, out of the January 2014 cycle, 3 babies were born being one boy and 2 girls, whilst from the March 2014 cycle, 9 babies were born consisting of 6 boys and 3 girls.



This shows that from the live births born in 2014 from IVF cycles there were a total of 18 boys and 12 girls. This is equivalent to 60% boys and 40% girls.




Conclusion

This report shows that the trend in Malta is that IVF procedures are increasing considerably with 170 cycles carried out in 2014 compared to the 100 carried out in 2013. This is also a reflection of the introduction of the Government funded cycles that are offered for free from the Public Hospital Mater Dei.


It is also a positive note that there has also been an increase in the success rate from IVF cycles, which was of 28.00% in 2013 and now in 2014 has increased to **28.82%** from all cycles carried out and to **30.82%** from embryo transfers carried out.

The Authority has and will keep constant contact with all Clinics providing guidance and help to see that these positive trends continue.

Moreover the Embryo Protection Authority intends in the near future to propose amendments to the principle Act and its own Protocol, following consultation with all stakeholders, so as to bring it in line with new medical developments, and other developments emanating to a large extent from foreign Constitutional judgements and those of the European Court of Human Rights in Strasbourg.



Judge Philip Sciberras
Chairman



Ms Simone Attard
Vice Chairperson