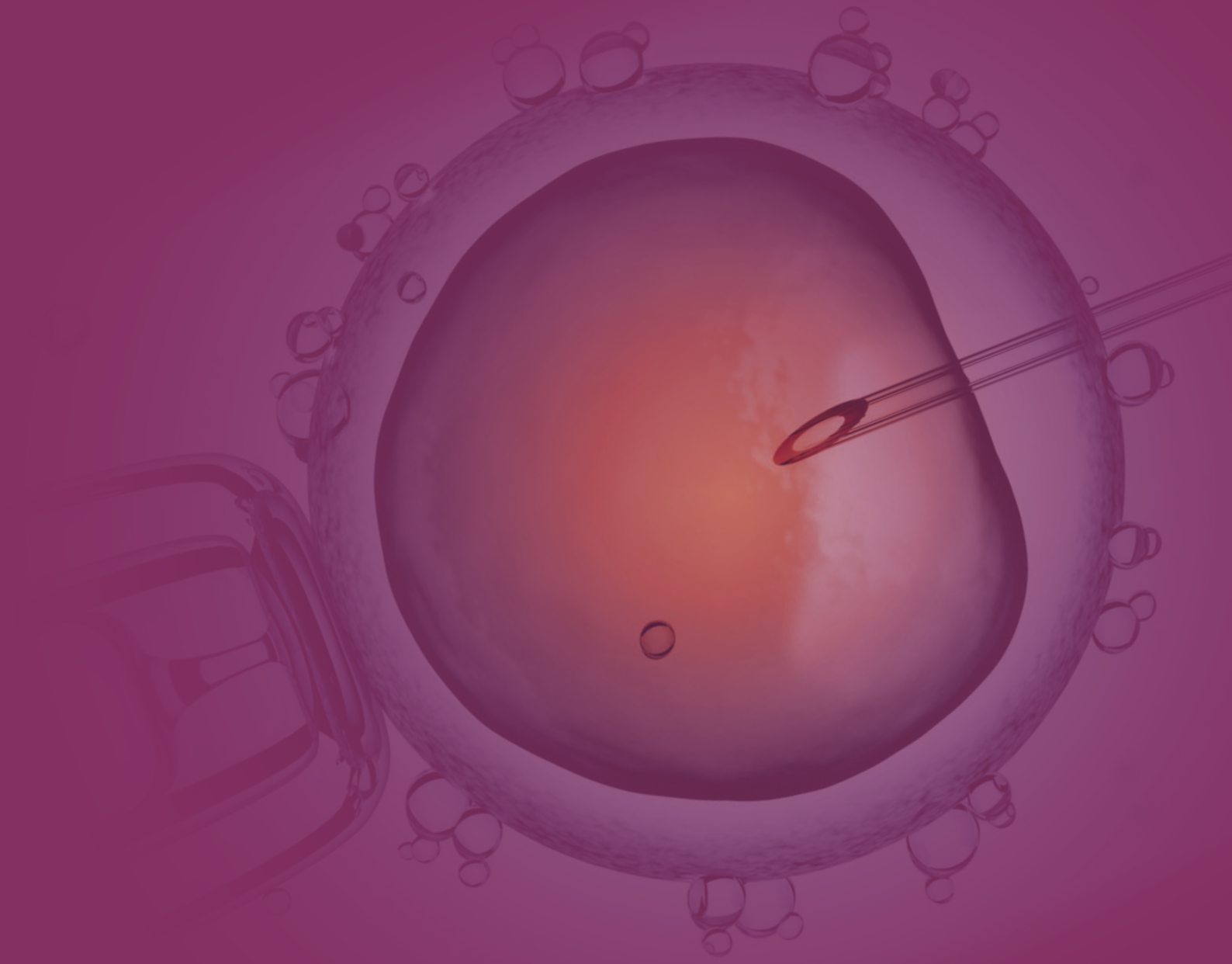
ANNUAL WORK REPORT

TRENDS AND FIGURES OF FERTILITY TREATMENTS IN MALTA FOR 2017



EMBRYO PROTECTION AUTHORITY

Putting Patients First

FEBRUARY 2018

ANNUAL WORK REPORT

TRENDS AND FIGURES

OF FERTILITY TREATMENTS

IN MALTA FOR 2017

EMBRYO PROTECTION AUTHORITY

Putting Patients First

Presented to Deputy Prime Minister and Minister for Health Hon. Chris Fearne

As per Embryo Protection Act 2012, Chapter 524

and

Embryo Protection Authority Regulations, LN32 of 2015

February 2018

EMBRYO PROTECTION AUTHORITY

PUTTING PATIENTS FIRST

ANNUAL WORK REPORT FOR 2017

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1. BACKGROUND

1.1. The Embryo Protection Authority (EPA)

The Embryo Protection Authority is a body corporate having a distinct legal personality and is the sole Regulator of all Assisted Reproductive Technologies (ART) performed at both the public and private licensed clinics/hospitals in Malta. It has been established as per the Embryo Protection Act 2012, (Chapter 524) which covers the use and storage of sperm, oocytes (eggs), and embryos for human application. The Authority sets the standards and determines the policy framework (Protocol) while providing information to stakeholders, the general public, and to couples seeking treatment.

1.2. Our Principles – PATIENTS FIRST

The Embryo Protection Authority treats all couples referred by the licensed Clinics with dignity and respect, and all information provided to the Authority in confidence remains highly confidential and disclosed only in the circumstances permitted by law, as per the Data Protection Act.

All decisions taken by the Embryo Protection Authority are taken in the best interest of the couples and of the child/children who may be conceived out of any assisted reproductive technology procedure undertaken.

1.3. Our Principles – Working closely with Stakeholders

The Authority ensures that the highest levels of standards are being kept as specified in the laws governing the fertility sector by working closely with all stakeholders in the Fertility field.

The Authority also performs its functions consistently and fairly with all clinics as per the established Laws and Regulations.

1.4. The Legal Framework

A number of laws and regulations make up the regulatory framework which covers the Assisted Reproductive Technology (ART) activities held in Malta.

1. *The 'Enabling' Act*:

The Embryo Protection Act 2012 – Chapter 524 of the Laws of Malta is the 'Parent' Act governing the Fertility Sector. The Bill was passed through Parliament and provides for the protection of human embryos through the establishment of the regulatory Authority (The Embryo Protection Authority).

2. *Regulations*:

The Embryo Protection Authority Regulations 2015 – (L.N.32 of 2015 – Chapter 524) have been published by Legal Notice following assent by the then Parliamentary Secretary responsible for Health. It grants the Authority its legal personality and representation, and outlines the executive administration and organisation of its affairs.

3. *The 'Protocol' and European Tissues and Cells Directive*:

The Protocol which was published by the Authority in 2013 is intended as a means of assisting licensed Clinics to comply with their legal obligations whilst also serving as a useful reference for patients and professionals working in the fertility sector.

Professionals working in the fertility sector are also bound to follow Directive 2004/23/EC which sets standards for donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells.

1.5. Functions of the EPA

- To ensure that high standards of ethics are maintained by all medical practitioners, paramedics, and other personnel involved in procedures of medically assisted procreation;

- To request and obtain, in cases of reasonable suspicion that the provisions of the Embryo Protection Act are not being followed, information and copies, in any form, of documents required by the Commission Directive 2004/23/EC of the European Parliament and of the Council of 31 March, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells to ensure traceability of human cells;

- To carry out inspections 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 Embryo Protection Act is being kept appropriately, and for this purpose to access clinics and any other places as necessary;

- To maintain a statement of the general principles which, in its opinion, should be followed in:

  a. Carrying out its activities under the Embryo Protection Act; and
  b. Carrying out its functions in relation to such activities under the Embryo Protection Act.

- To ensure, in relation to activities under the Embryo Protection Act, compliance with:

  a. The obligations and requirements imposed by or under the Embryo Protection Act;
  b. The codes of practice established under paragraph (a) of the Embryo Protection Act.

- To perform such other functions as may, from time to time, be prescribed by regulations made under the Embryo Protection Act.

1.6. Human Resources

During 2017, the Authority strengthened its inspectorate function through the engagement of one inspector who has already received training locally and will be given further training abroad in the first quarter of 2018.

The Authority strives to ensure that its employees have the skills and competences to match the organizational requirements in order to guarantee optimal executive performance. The Executive Director, Deputy Head, and the Executive Officer received regular training throughout the year. The Executive Director has successfully completed and graduated in the Public Management Toolkit which is being offered by the Institute for Public Services (IPS). She has also successfully completed her training on EU Fund Management.

The Deputy Head and Executive Officer have attended to training on Data Protection Awareness in preparation of the new General Data Protection Regulations coming into force. The Executive Officer attended to various other courses offered by the IPS.

In January, the Executive Director and Deputy Head were present for a Campus Symposium on 'The Effects of ART and endometriosis on pregnancy Outcome'. This Symposium was organised by the European Society for Human Reproduction and Embryology (ESHRE), and took place in Sofia, Bulgaria.

In July, the Deputy Head of the Authority attended the ESHRE Annual Conference held in Geneva, Switzerland including a Pre-Congress course.

In September 2017, the Executive Director was invited to receive training and give her contribution at the ARTHIQS (Assisted Reproductive Technologies and Haematopoietic stem cells Improvements for Quality and Safety throughout Europe) dedicated for ART Competent Authorities. This is a 3 year European Joint Action funded by the European Commission under the Health Programme, dealing with Assisted Reproductive Technologies (ART) and Haematopoietic Stem cells for transplantations. ARTHIQS brings together 16 partners and 9 collaborators from 18 different Member States. Training was held in Stockholm Sweden. This was followed by a Final Technical Meeting for Competent Authority Members which discussed the sensitive issues of cross border reproductive care in ART.

Last November, the Executive Director attended a meeting held in Brussels for the EU Competent Authorities on Substances of Human Origin Expert Group which was convened to discuss the Transposition of Tissue and Cells Directives, Update on the Joint Action ARTHIQS - Good practices on donation, collection, testing, processing, storage and distribution of gametes for Assisted Reproductive Technologies and of haematopoietic stem cells for transplantation. Update on the Joint Action VISTART - Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation. The issues of Surveillance and Vigilance were also discussed. International Updates from the Council of Europe and WHO were also presented for discussion. The meeting ended with interaction with several

ART stakeholders and Non-Government Organisations who presented various presentations on cryopreservation, genetic testing and couple support.

The Ministry for Health had assigned new premises to the Authority in 2016, after the necessary refurbishment works will be completed, hopefully in 2018, EPA will move out of its one-room office in St Luke's Hospital and shall relocate to its new assigned offices at the ex-CPSU building in Pieta.

1.7. Board Members and Executive Administration

The legal representation of the Authority is vested in its Chairman, Hon. Judge Emeritus Philip Sciberras UOM. The other appointed members include Dr. Patrick Sammut MD MRCPCH MSc., Ms. Mariella Meachen B. Psych (Hons) MA (Psychotherapy) R.N., and Ms. Pauline Baldacchino MSc. (Psych) B.A. (Hons) B.A. PGCE PGDip Couns. PGDip Psych. MBPsS.

Since Ms. Simone Attard's appointment as Executive Director, the Vice-Chairperson's seat had remained vacant. All the members of the Board have been appointed on the 17th May 2013, as per Article 3 of the Embryo Protection Act. Following the announcement of a General Election, all Board members submitted their resignations but continued to perform their duties until their resignation was acknowledged or else they were re-appointed. Further details of the new composition of the Authority's board members are given further below.

During 2017, seven board meetings have been called and in all sittings quorum was achieved. Attendance by the members and Executive Director to these Board meetings were as stated hereunder:

Designation	Name	Attended	Excused
Chairperson	Judge Philip Sciberras	7	0
Member	Dr. Patrick Sammut	5	2
Member	Ms. Mariella Meachen	7	0
Member	Ms. Pauline Baldacchino	5	2
Director	Ms. Simone Attard	7	0

Eight meetings with Representatives from *the Obstetrics and Gynaecology Association* and the *Paediatric Association of Malta* have been called in order to discuss requests for the additional fertilization of oocytes. These requests are made by the clinicians treating the couples. [Article 6 of the Embryo Protection Act gives the power to the Authority, in consultation with the aforementioned Associations, to approve the fertilization of three oocytes instead of the two currently permitted by law]. A further meeting, between the representatives of the Associations, was held to discuss necessary changes to the current criteria in place for the fertilization of three oocytes. The Authority was represented by Dr. Patrick Sammut in this meeting. A report is to be presented to the Authority in the coming months with the necessary recommendations.

On the 20th December 2017, a new Embryo Protection Authority Board was appointed in terms of Article 3 (1) of the Embryo Protection Act 2012, (Chapter 524) to serve for three years up to 19th December 2020 and was composed as follows, Chairman, Hon. Judge Emeritus Philip Sciberras UOM., Vice-Chairperson Ms. Josephine Abdilla MBA *Henley,* DIP Mang. *Henley.* The other appointed members include Dr. Patrick Sammut MD MRCPCH MSc., Ms. Mariella Meachen B. Psych (Hons) MA (Psychotherapy) R.N., Profs. Victor Grech MD PhD. PhD FRCPCH FRCP, and Ms. Sarah Camilleri Dip Economic and Political Studies. The newly composed board will meet for the first time in January 2018.

In exercise of the powers conferred by Article 6 (2) of the Embryo Protection Authority Regulations, 2015 (L.N. 32 of 2015), the Hon Minister for Health, after consultation with the Embryo Protection Authority has appointed Ms. Simone Attard PGrad Cert, PGrad Dip Systemic Practice (Tavistock and Portman NHS Trust UK)., MBICA., as Executive Director of the Embryo Protection Authority to serve for a second term of three years up to 31st January 2021.

1.8. Annual Remuneration to Board Members

The members of the Board are not fully employed by the Embryo Protection Authority but receive annual remuneration for their services, as listed overleaf:

Designation	Name	Annual Remuneration (Euros)
Chairperson	Judge Philip Sciberras	13,954
Member	Dr. Patrick Sammut	3,494
Member	Ms. Mariella Meachen	3,494
Member	Ms. Pauline Baldacchino	3,494

1.9. The Authority as a Regulator

As the sole regulator of all Assisted Reproductive Technologies (ART) performed at both public and private licensed clinics/hospitals in Malta, the Authority strives to ensure compliance with the obligations and requirements imposed by or under the Embryo Protection Act and Protocol. Throughout 2017, the Authority has received requests from the Clinics to grant permission to specific couples to undergo the IVF/ICSI procedure despite the female patient being of an age which falls outside the bracket specified in the Protocol. All the requests were turned down as they constituted a serious breach of the Protocol.

In March 2017, the Authority was informed by the Attorney General's Office that one couple had instituted a constitutional application at the Civil Court against the Attorney General and the Embryo Protection Authority. The Chairperson and Executive Director gave evidence in this case. Case is still ongoing.

Throughout 2017, the Authority was also notified of five separate incidents which occurred at the licensed Clinics. The first one occurred late in 2016 and was reported in January 2017. The incident involved frequent top up of liquid nitrogen due to a leak in one of the storage dewars. Risk assessment was performed by the Clinic and the issue was addressed by procuring two new storage dewars for cryopreservation.

The second incident involved a multi-chamber incubator which contained 18 embryos still in incubation. The Authority was informed that the embryologists, on entering the ART Laboratory in the morning, had found the multi-chamber incubator switched off.

This Serious Adverse Event (SAE) was immediately reported to the Authority who requested that: (a) all prospective parents involved are informed on individual basis of the situation with all the possible risks and outcome of embryo transfer, (b) all professionals involved in process must draw up a detailed report of the incident. The Authority also requested the Department of Health to initiate an Internal Investigation / Inquiry to determine the exact cause of the Incident. Later on, in the same day Minister for Health Hon. Chris Fearne, informed that an Independent Inquiry had been ordered. Inquiry is still ongoing and the Authority awaits outcome of same.

The third incident involved a UPS supply interruption which affected some of the equipment in the ART laboratory. The power cut lasted only a few minutes so no damage was incurred. Incident happened when embryologists were present in the lab, thus it was immediately controlled. Measures were initiated

to install further external UPS systems to avoid same incident happening again.

Two other incidents were reported involving admission of two patients in hospital for observation and investigation due to mild Ovarian Hyperstimulation Syndrome (OHSS). Patients were admitted to hospital post oocyte retrieval, however as both cases were mild OHSS, fertilisation could take place and patients were fit for embryo transfer. Incidents were resolved as per Stimulatory Treatment Protocol. The Authority however brought to the attention of the licensed clinic that OHSS cases are to be reported immediately to the Authority, these two particular cases occurred in March 2017 and were reported two months later in May 2017. The Authority insisted that strict adherence to the Protocol is to be maintained.

In December 2016, the Authority was notified that a couple, who attended infertility counselling and were due to undergo the procedure in the following month, appeared to have relationship issues. In view of the fact that the welfare of the child who might have been conceived out of the IVF/ICSI procedure could not be guaranteed, the Authority referred the couple for further counselling before their application could be reconsidered. The Authority continued to monitor this case and in August 2017, after receiving a detailed psychotherapist report, the Authority reviewed the case and approval was granted to the couple to undergo IVF cycles.

Back in October 2016, the Authority had received a request for the freezing of two embryos which due to a *force majeur* not predictable at the time of

fertilization, could not be transferred on the day of the planned embryo transfer as the mother was very unwell. The request was immediately approved by the Authority. The two embryos are still in storage until the prospective mother is fit to undergo embryo transfer.

The Authority has received five requests from the licensed clinics to grant permission for oocyte retrieval and cryopreservation only, from five women aged between 22 and 42, who wanted to preserve their fertility. Four permissions were granted on the grounds that these women were already in a relationship, the other request concerning a 22 years old lady was granted permission on medical grounds due to Premature Ovarian failure. Out of the five permission granted only four had successful oocyte retrieval and cryopreservation, one patient did not undergo oocyte retrieval due to medical reasons.

1.10. ART Prioritization Committee

The Ministry for Health considers the fact that couples requiring IVF cannot be waitlisted on a *first come-first served* basis. To this effect, the Ministry appointed an ART (Assisted Reproductive Technology) Prioritization Committee with the aim of objectively ranking in order of precedence the couples who are seeking assistance at the ART Clinic at Mater Dei Hospital (MDH). Each clinical case is considered individually and priority of treatment is given to couples where female age is an issue, since delays in providing an opportunity for treatment may make the couple ineligible for future treatment. Other factors, such as AMH levels, semen parameters, paternal age, duration of infertility, previous failed IVF/ICSI attempts, recurrent miscarriages, etc., are

also taken into account. During 2017 the Authority was represented on this Committee by its Executive Director Ms. Simone Attard and by Dr. Patrick Sammut as member.

The ART Prioritization Committee was re-composed on the 18th December 2017, Ms. Simone Attard, the Executive Director was re-appointed to serve on this Committee, Profs. Victor Grech was appointed as member.

In view of the fact that new cases are registered at Mater Dei Hospital every week, this Committee met on a monthly basis to decide which of these couples requires prioritization for treatment. Five reports were consequently issued showing a total of 158 couples that had been reviewed by the ART Prioritisation Committee during 2017.

1.11. Inspections

The Authority, together with the Superintendence of Public Health (SPH), from time to time makes the necessary inspections so as to ensure that there are no infringements of the provisions of the Act or the Regulations, or of the Protocol which the Authority is entitled to enforce. These inspections are held in order to make certain that the standards of best practice are being respected and implemented, that the documented system which ensures the identification of all gametes and embryos from procurement to use is in place, and that the storage and consignment of gametes from one centre to another is verified against Standards of Practice (SOPs) and third party agreements, as required in the EU Directive.

In 2017, inspections were carried out at the ART Clinic in Mater Dei Hospital and at the Assisted Conception Unit in St James Hospital. These were in conformity with the legislative requirements for periodic re-inspection before renewing the licence. The Assisted Conception Unit in St James Hospital was issued with a renewal licence valid up till 31st December 2018. The ART Clinic in Mater Dei Hospital was issued with a renewal licence valid up till 11th June 2019. The inspection at the ART Clinic in Mater Dei was observed by the Deputy Head of the Authority. No request was made by the Superintendence of Public Health, for a representative of the Authority to accompany SPH for the inspection of the Assisted Conception Unit at St James Hospital. The Authority wrote to the Superintendent of Public Heath, informing that this is unacceptable as the Authority is the Regulator of the ART Sector and should be present. The Authority also requested to be forwarded with a copy of the inspection report held and with a copy of the new licence that was issued.

1.12. Other work by the Authority

Apart from the normal processing of all applications for treatment, requests for additional fertilizations, and the storage of gametes (a detailed report to follow), the Authority was in continuous communication with the Ministry for Health in order to provide the relevant information in answer to the several Parliamentary Questions (PQs) repeatedly made on the ART procedures offered on the NHS, and the Eligibility Criteria as established in the Embryo Protection Authority's Protocol.

The Embryo Protection Authority, through its Executive Director, was also in continuous discussion with the Ministry for the Family and Social Solidarity and the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties, regarding the introduction of new Budgetary Measures related to Assisted Reproductive Technologies so as to ensure compliance with the Authority's Protocol. To this effect a Legal Notice was issued on the 31st May 2017, granting Special Leave for Medically Assisted Procreation.

In addition to the monitoring of ART services given to patients by the licensed Clinics, the Authority also supervises the storage of gametes. A Gamete Storage Inventory (Dewar mapping) which stretches back to the date of first cryopreservations (July 2013), is kept by the Authority. This serves to ensure that storage of gametes is being properly documented so as to guarantee traceability.

Together with the SPH, the EPA strives to make sure that each licensed Clinic adopts a Quality Management System that is in line with the EU Directives and Human Tissues and Cells Local Legislations related to the ART services.

In view of the fact that the Authority processes personal data, in 2017 it took the necessary measures to be in conformity with the Data Protection Act, and duly registered its operations with the Commissioner for Data Protection and also appointed a Data Protection Officer to take care of Data Protection issues.

In 2017, the Authority took the initiative to start the process of implementing an Innovation Programme by launching a new website dedicated solely to the Authority and also in moving a step further so that all fees due to the Authority are settled directly online. Another ambitious programme taken on board is the undertaking of a Business Analysis of the Authority's operational side.

The Authority's website was launched on the Ministry for Health's portal, though continuous collaboration with the Information Management Unit of the Ministry for Health. The website contains the Authority's Mission Statement, details about the Entity's Corporate Identity, Board Members and Executive Administration together with an Organisation Chart. All publications of the Authority have also been uploaded and these include: The Act and Legal Notices, EU Directives, Authority's Protocol and all Annual Reports issued to date. The website can be accessed on www.epa.gov.mt .

In March 2017, all the setup required for the direct payment of fees came into place and with immediate effect all fees, whether licence fees, procedure fees or storage fees were being filed through direct transfer from the licence operators to the Authority.

By December 2017, the Business Analysis was also finalised. This Analysis included also a Business Process Re-Engineering and the formulation of Technical Specifications related to Information Systems at the Authority. All the necessary reports were presented to the Authority and to the Chief Information Officer (CIO) of the Ministry for Health, these included a

Recommendations Report, Business Process Re-engineering Report and a Business and Technical Specifications Report.

In the first quarter of 2018, it is envisaged that a new tender is issued for the procurement and implementation of a new IT system based on the above Technical Specifications Report that will link the Authority with all licensed clinics both private and public so all documentation can be filed on-line thus enabling the Authority to have real time data.

Pursuant to the EPA Regulations of 2015, the Authority is taking the necessary measures towards becoming fully autonomous.

The Minister for Health, on the 22nd March 2017, laid on the Table of the House of Representatives EPA's Audited Accounts for 2016 and Financial Estimates for 2017 and 2018, together with the Authority's Annual Report for 2016. A Parliamentary debate on the Authority's finances was held in one sitting on the 30th of June 2017.

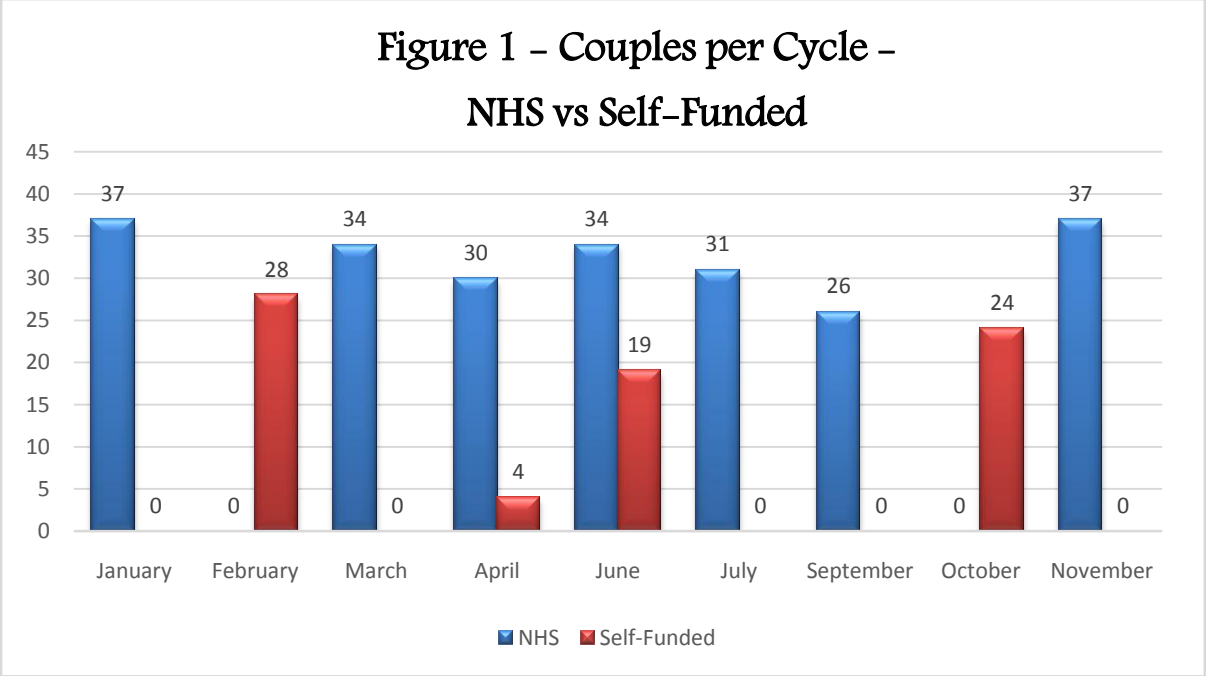
FERTILITY TREATMENTS IN MALTA FOR 2017 – TRENDS AND FIGURES

In line with LN32 of 2015 and the Embryo Protection Authority's Protocol which has been prepared in accordance with the Embryo Protection Act 2012, clinics in both the private and public sector are bound to provide the Authority with accurate data about their activities. This data is held on the Authority's Register of ART Procedures and the accuracy of this report is based on the information provided by the Clinics as at 31st January 2018.

2. CYCLES PERFORMED

Throughout 2017, the Authority has received a total of 309 applications from clinics in both the private and public sector. All applications have been approved and thus 309 cycles were carried out, these were divided into 5 patients having a cycle where oocytes were retrieved and cryopreseved only so no IVF procedure was carried out, the other 304 underwent an IVF/ICSI procedure.

Two hundred and twenty nine (229) procedures have been carried out at the ART clinic in Mater Dei Hospital (MDH), and seventy five (75) cycles were performed in the private sector at the Assisted Conception Unit in St James Hospital (Figure 1).



The number of IVF/ICSI procedures carried out in Malta in 2017 increased by 11.35% over the previous year, which is mainly attributed to the fact that more procedures were being carried out at the ART Clinic in Mater Dei Hospital.

2.1. First Time/Repeated Cycles

Out of the 304 cycles carried out, 49.7% of couples (151 couples) were undergoing the IVF/ICSI procedure for the first time. There were 31.6% of couples (96 couples) who were undergoing IVF/ICSI for the second time, 9.9% of couples (30 couples) for the third time, 6.6% of couples (20 couples) were undergoing their fourth attempt, while the remaining 2.3% of couples (7 couples) had undergone five or more cycles, out of which one couple had undergone their seventh attempt (Figures 2 and 3).

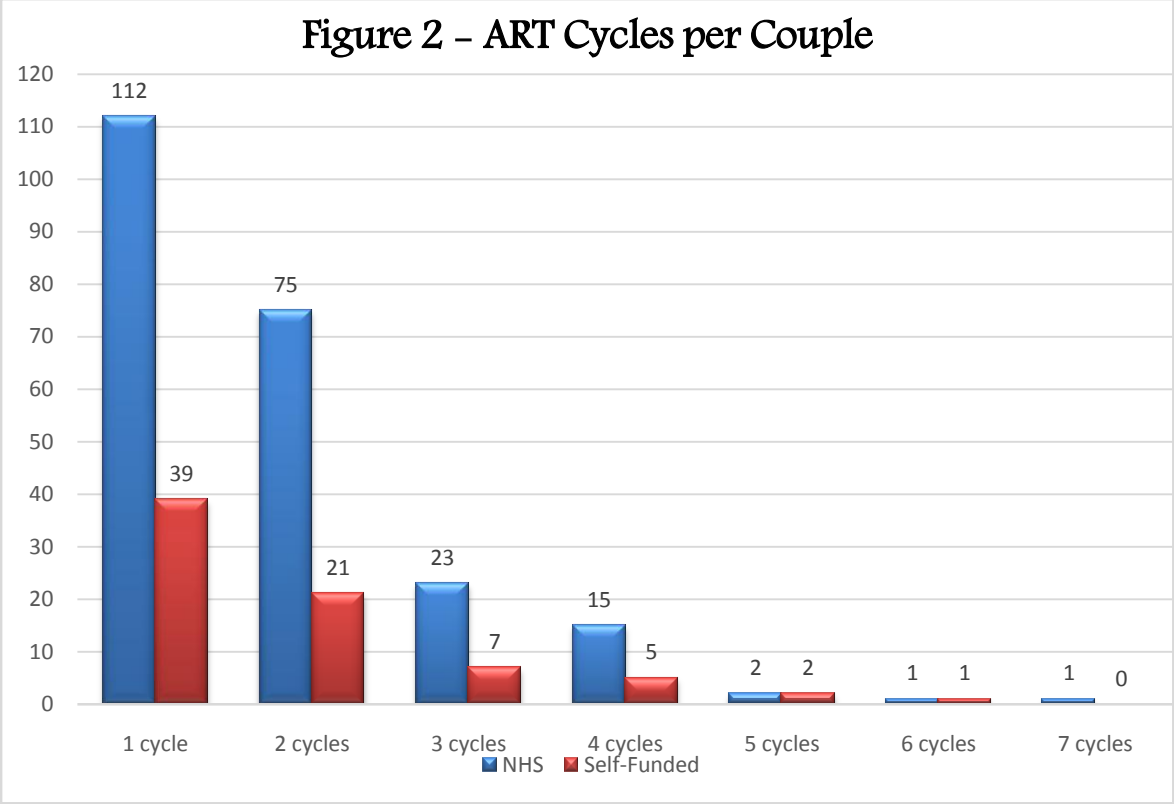


Figure 2 – ART Cycles per Couple
120
110
100
90
80
70
60
50
40
30
20
10
0
112
39
75
21
23
7
15
5
2
2
1
1
1
0
1 cycle
2 cycles
3 cycles
4 cycles
5 cycles
6 cycles
7 cycles
NHS
Self-Funded

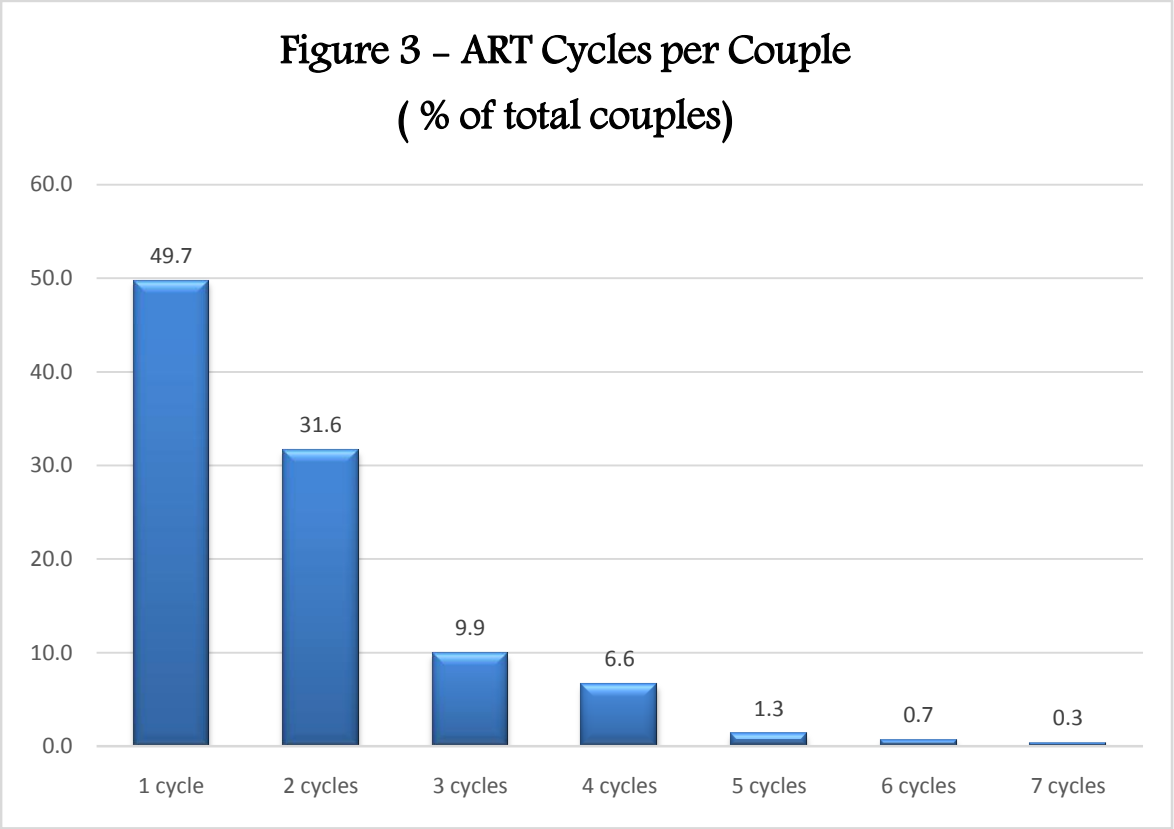
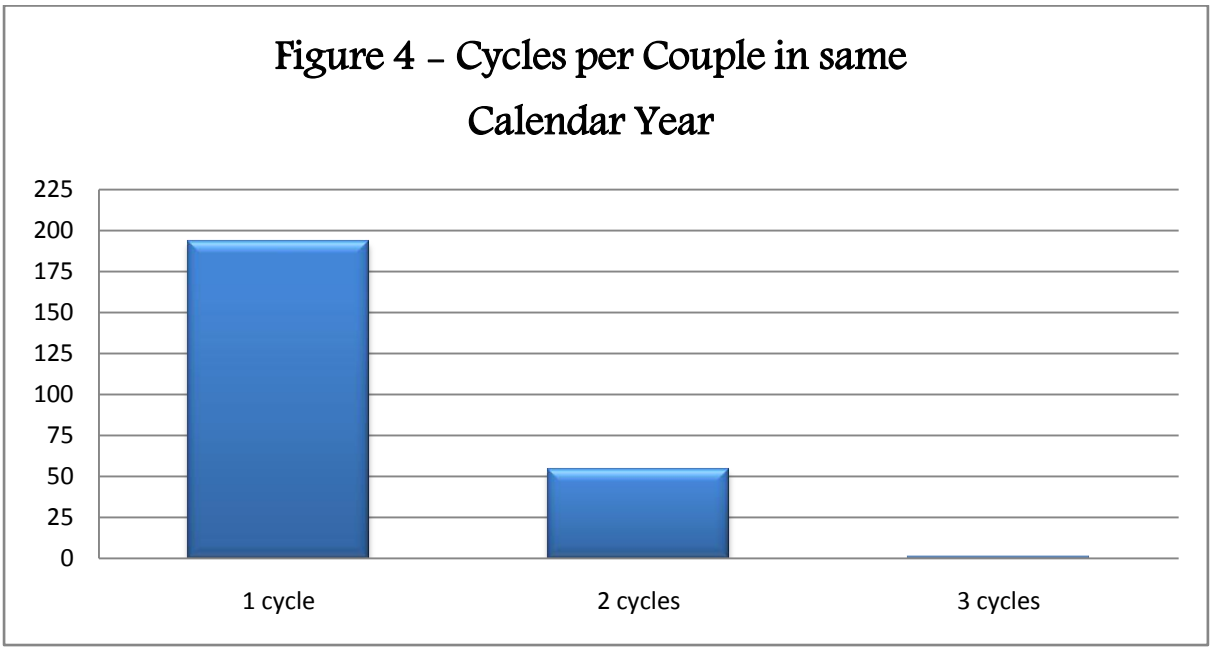


Figure 3 – ART Cycles per Couple
(% of total couples)
60.0
50.0
40.0
30.0
20.0
10.0
0.0
49.7
31.6
9.9
6.6
1.3
0.7
0.3
1 cycle
2 cycles
3 cycles
4 cycles
5 cycles
6 cycles
7 cycles

During the same calendar year in 2017, there were 193 couples who had undergone a single cycle, 54 couples who had undergone 2 cycles, and a single couple who had undergone three cycles during the same year. Thus, these 304 IVF/ICSI procedures were undertaken by 248 couples (Figure 4).



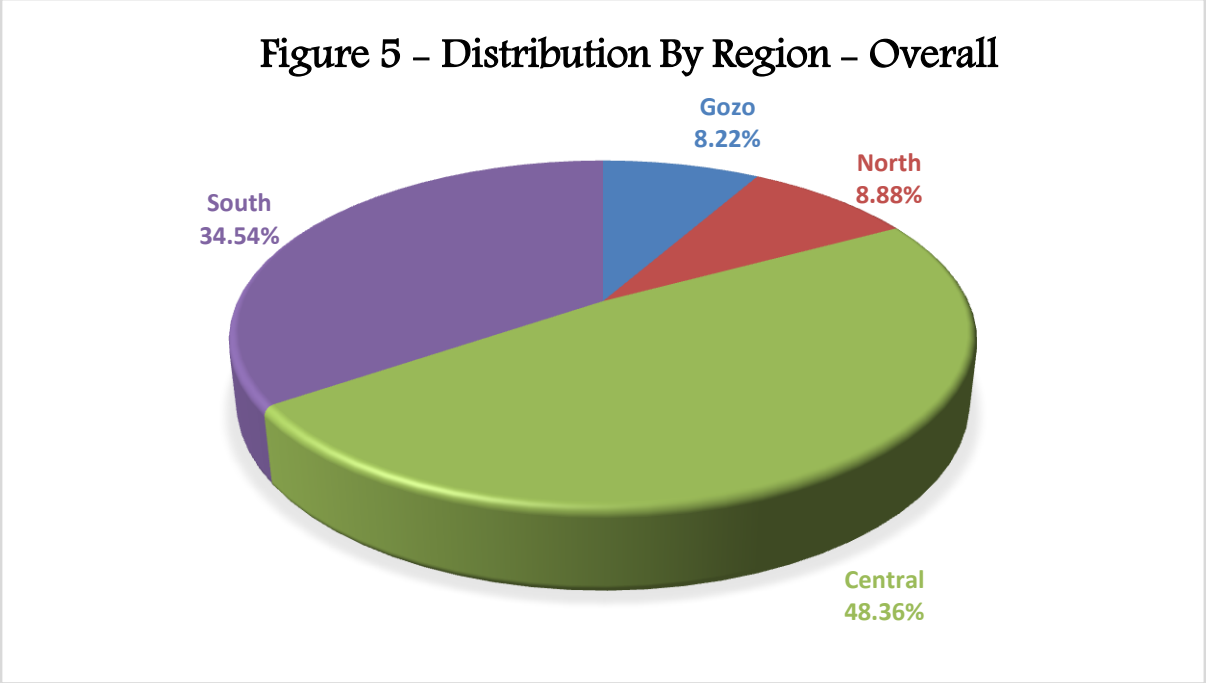
3. DEMOGRAPHICS

3.1. Nationality

All of the 304 cycles performed this year were undertaken by Maltese Residents. There were no foreign couples (non-Residents) who came to Malta specifically to perform the IVF/ICSI procedure in the private sector. This is consistent with last year wherein the private sector had reported a marked decrease in Medical Tourism in the Fertility sector when compared to 2015 and 2014, where the number of non-residents undertaking IVF/ICSI procedures amounted to 5 and 13 respectively.

3.2. Regions

As reported in previous years, the overall majority of couples 48.36% (147 couples) who had undergone IVF/ICSI procedures in 2017 reside in Central Malta, followed by 34.54% (105 couples) who reside in Southern areas of Malta, 8.88% (27 couples) reside in the Northern part of the island, while the remaining 8.22% reside in Gozo (Figure 5).



Worth nothing is the fact that when it comes to self-funded treatments, the majority of couples 56%, still come from the Central areas of Malta followed by 21.33% of couples who reside in the Southern part of the island, however this time the Gozitan couples 12% chose to self-fund their treatment more than couples 10.67% residing in the Northern part of Malta (Figures 6, 7 and 8).

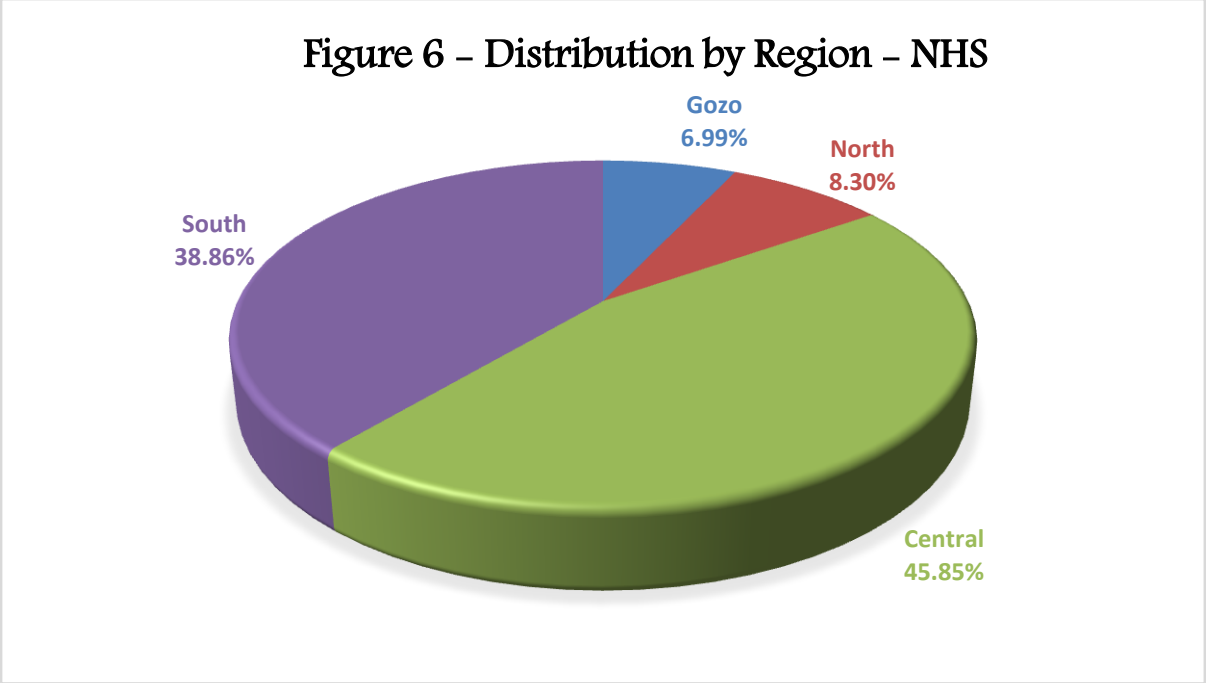


Figure 6 – Distribution by Region – NHS
Gozo
6.99%
North
8.30%
South
38.86%
Central
45.85%

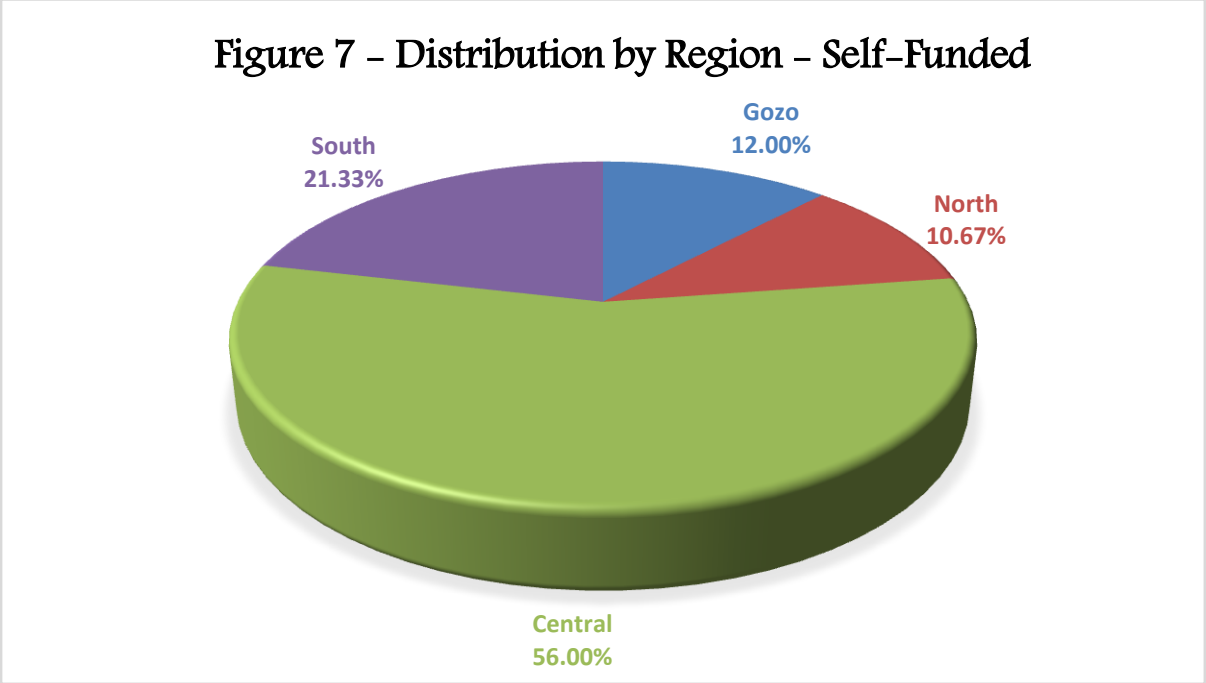
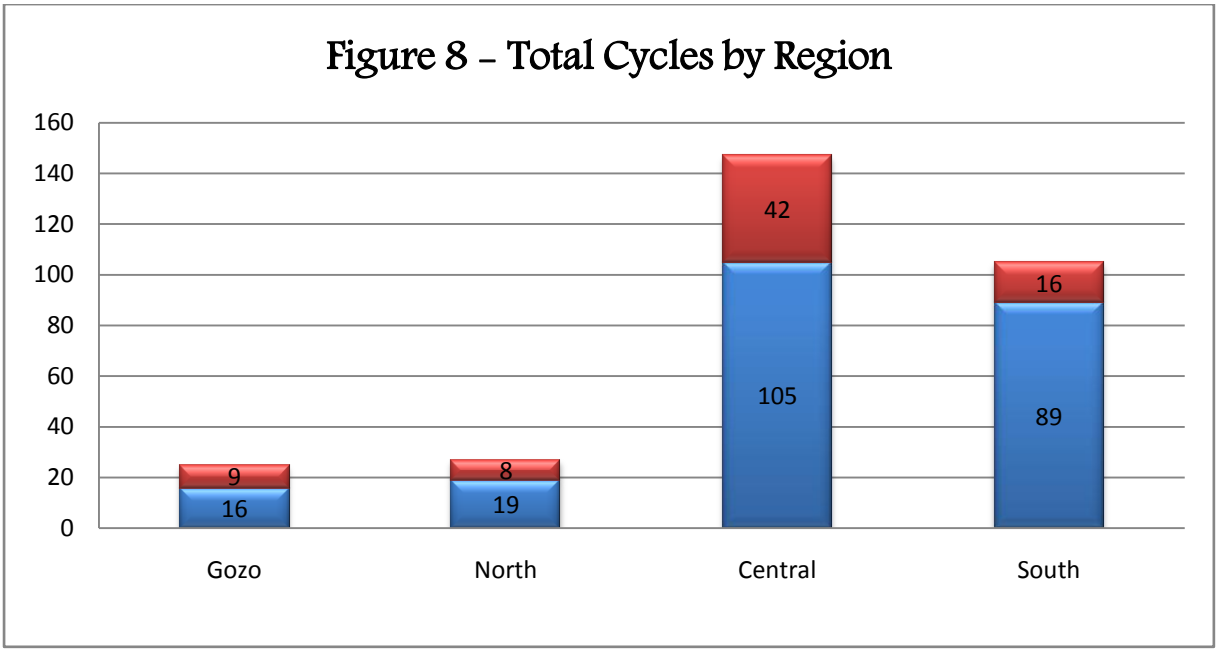


Figure 7 – Distribution by Region – Self-Funded
Gozo
12.00%
South
21.33%
North
10.67%
Central
56.00%



In 2017, only 20.83% of couples (25 couples) suffering from primary infertility who were undergoing their *first-ever* IVF/ICSI attempt, opted to self-fund their treatment, despite being eligible for treatment on the NHS (Figure 9). Figures 10 to 13 show the couples' funding preference per region.

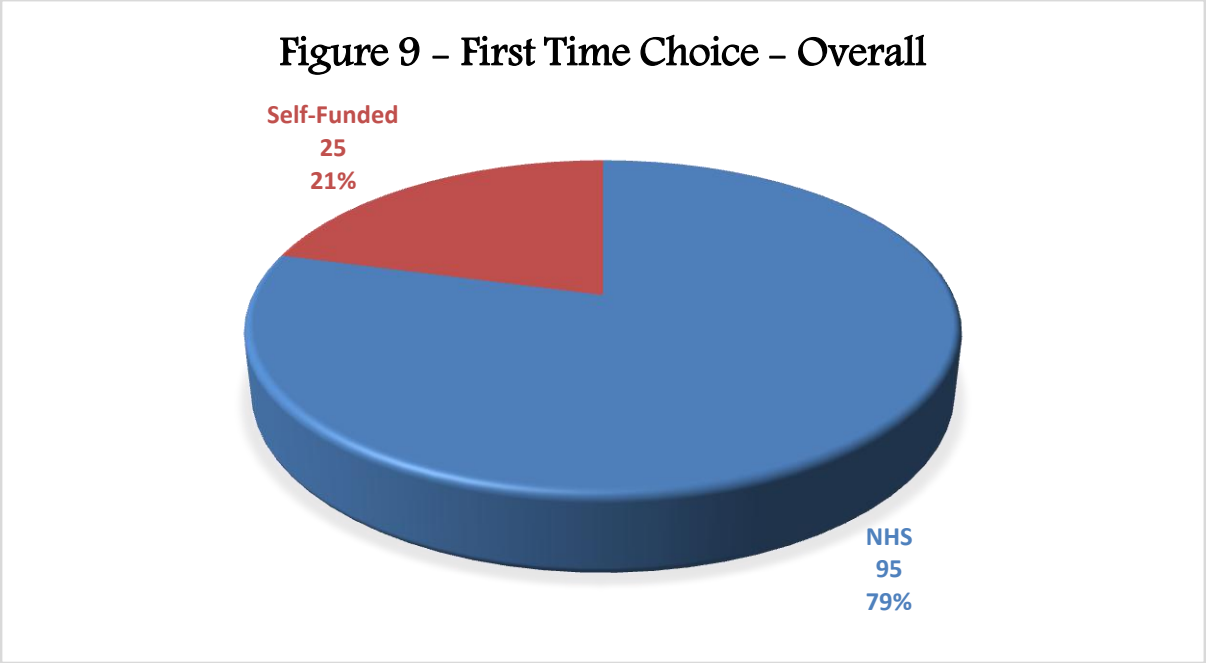


Figure 10 – First Time Choice – Gozo

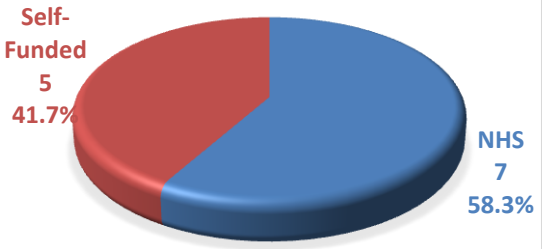


Figure 11 – First Time Choice – North

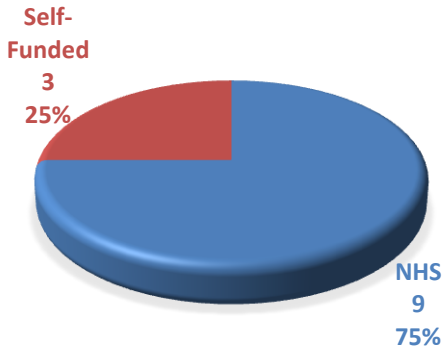


Figure 12 – First Time Choice – Central

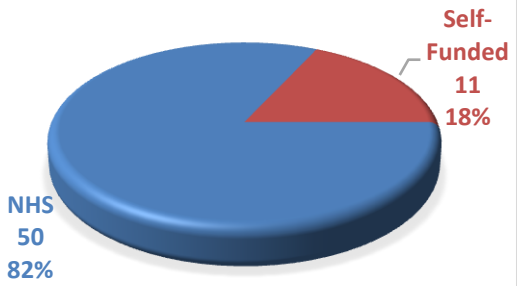
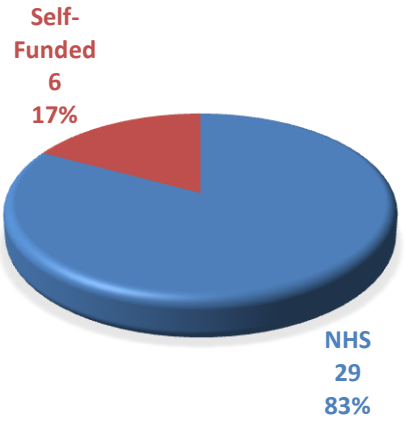
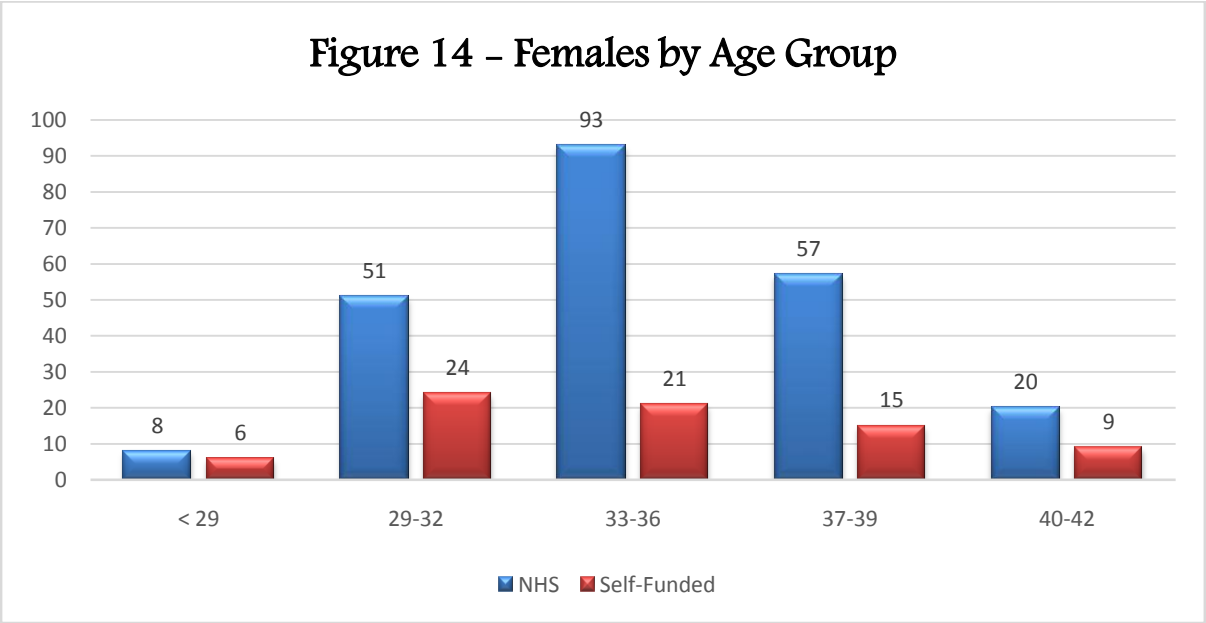


Figure 13 – First Time Choice – South

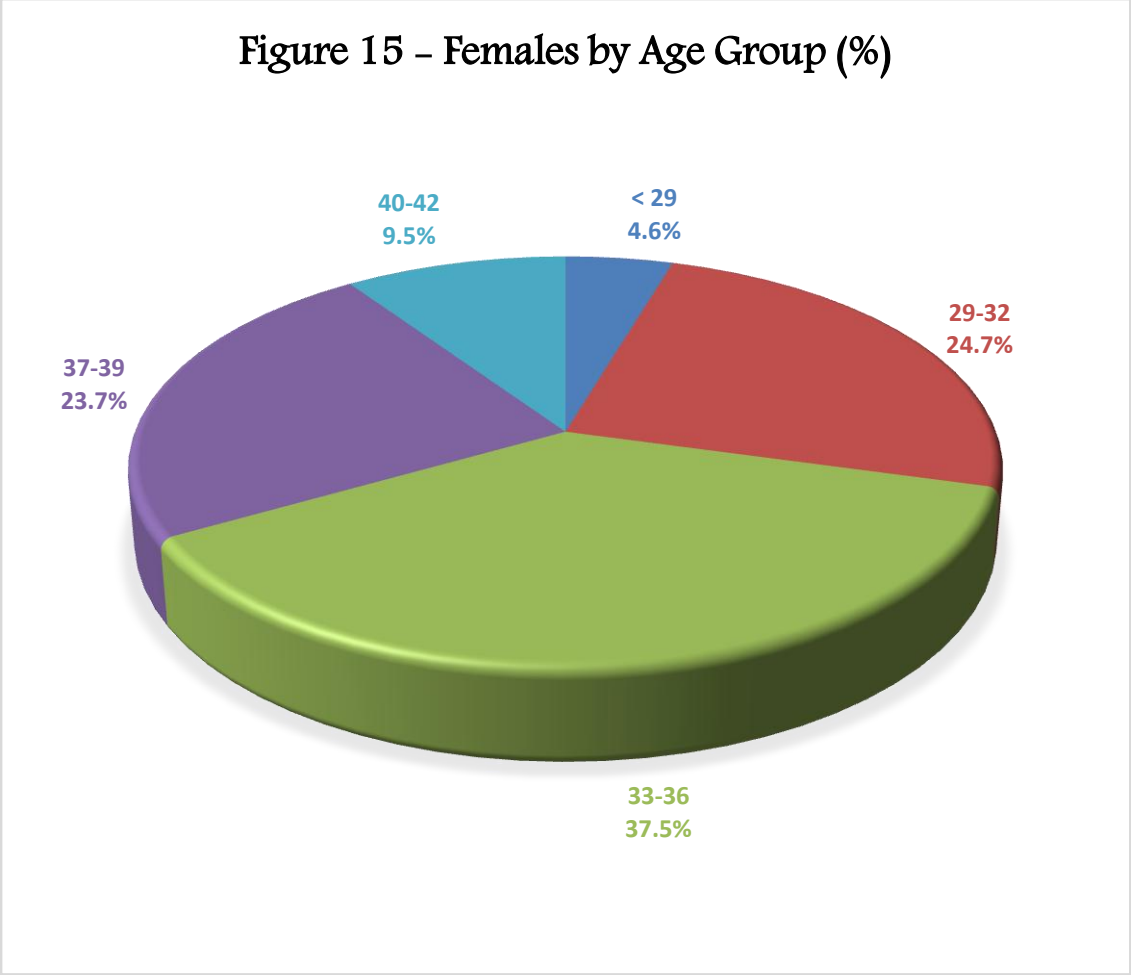


3.3. Maternal Age

In line with the Embryo Protection Authority's Protocol, in Malta, only women falling within the stipulated age bracket of 25 and 42 are eligible for IVF/ICSI procedures. Throughout 2017, there has been a distribution of procedures across all age brackets, as can be noted from the chart hereunder (Figure 14).



As for the past three years, the largest number of female patients, 114 females (37.5%) undertaking IVF/ICSI procedures throughout 2017 was aged between 33 and 36. The second largest age group was for female patients aged 29-32, 75 females (24.7%), while 72 females (23.7%) were in the 37-39 year old bracket. There were 29 female patients (9.5%) aged 40-42, while the remaining 14 female patients (4.6%) were under the age of 29 (Figure 15).

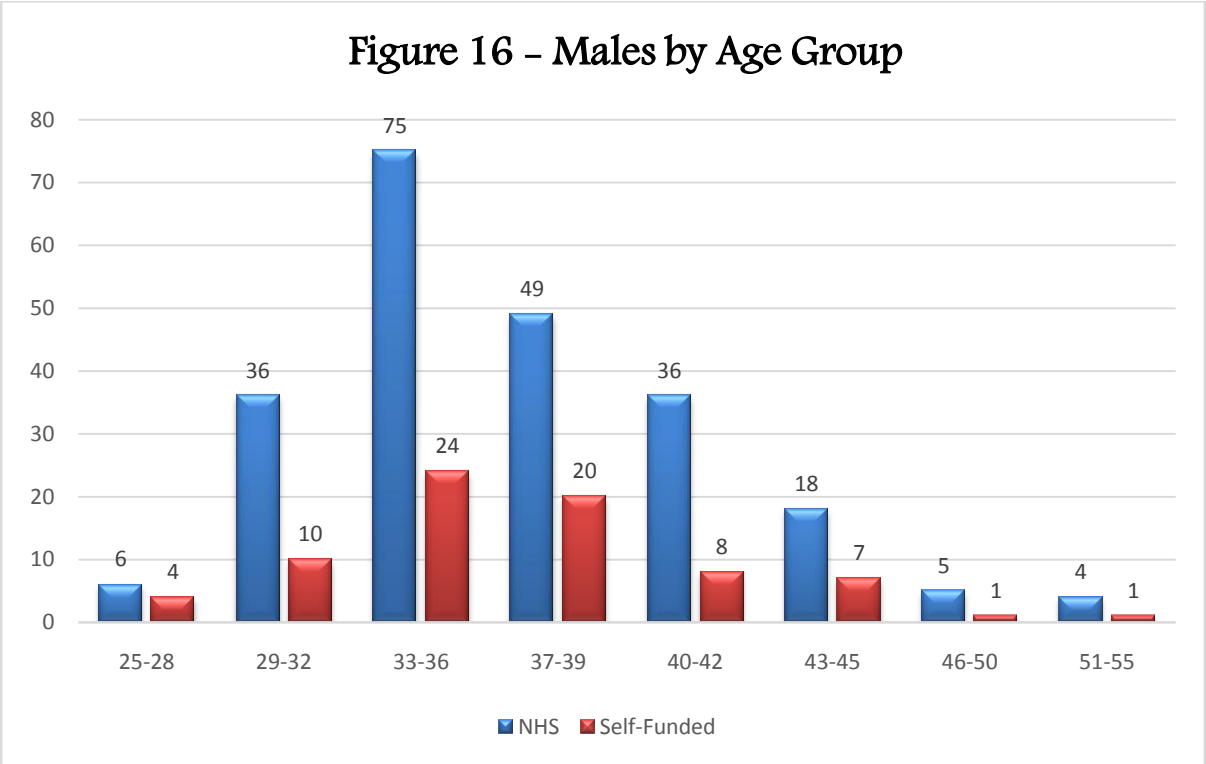


Noteworthy is the fact that in 2017 there has been a drop of 3.5% in both age groups of females aged 29 or less and of females aged between 29 and 32.

Conversely the age group of women aged between 33 and 36 registered an increase of 4.9%. The other two age groups registered a slight increase in females who had undergone IVF/ ICSI procedure.

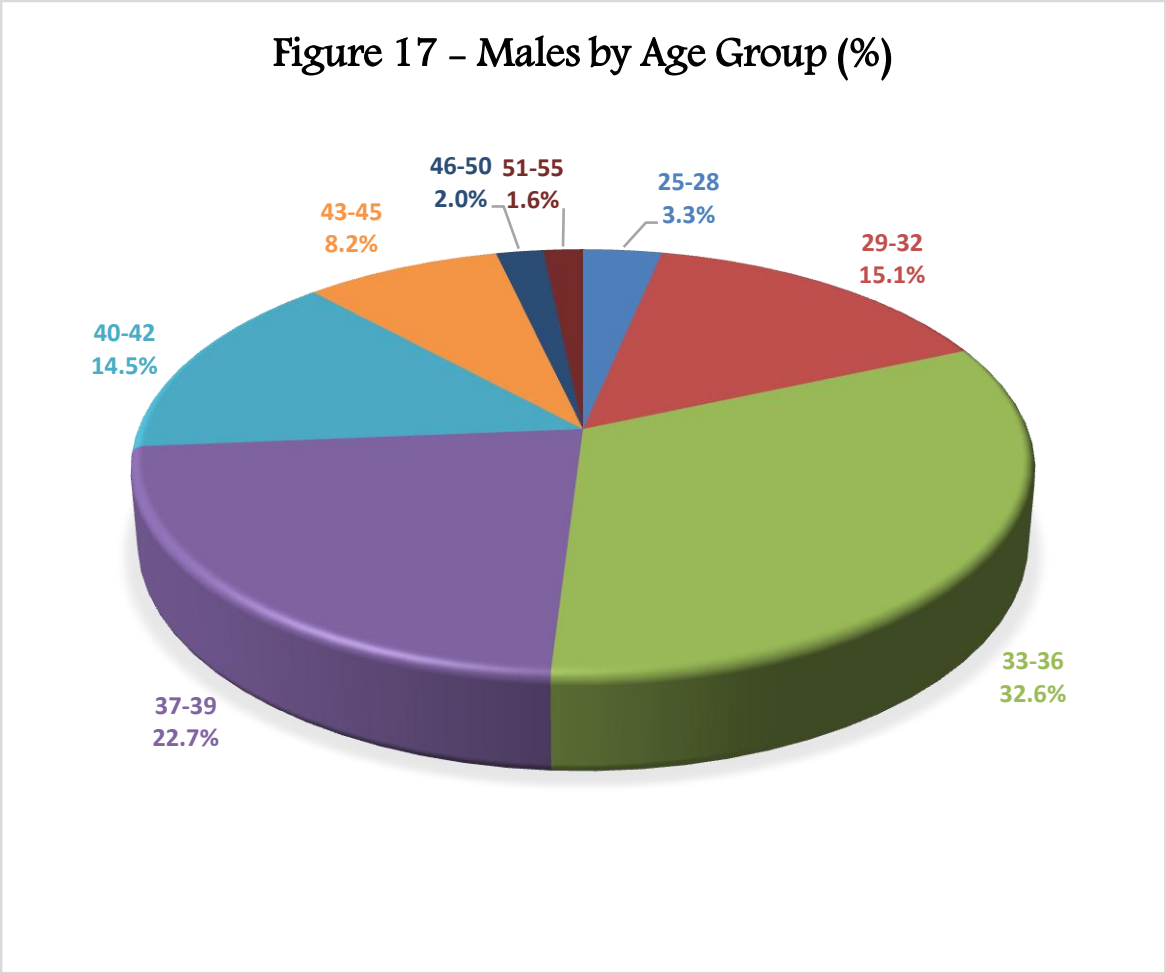
3.4. Paternal Age

As with the female patients, the largest number of male patients, 99 males (32.6%) undergoing procedures was in the 33-36 year old bracket, while 69 males (22.7%) were aged between 37 and 39. The third largest age group (15.1%) consisted of 46 males aged 29-32. Following closely at (14.5%) were 44 males in the 40-42 year old bracket. The male age group of males aged between 43-45 years was the fifth largest age group with 25 males (8.2%) while 11 patients (3.6%) of male patients were aged 46 years and over. The remaining 10 males (3.3%) of males were under the age of 29. (Figures 16 and 17).



Noteworthy is the fact that while in 2016 the oldest male was in the 56-60 age bracket, in 2017 the oldest male was in the 51-55 age bracket. In 2017

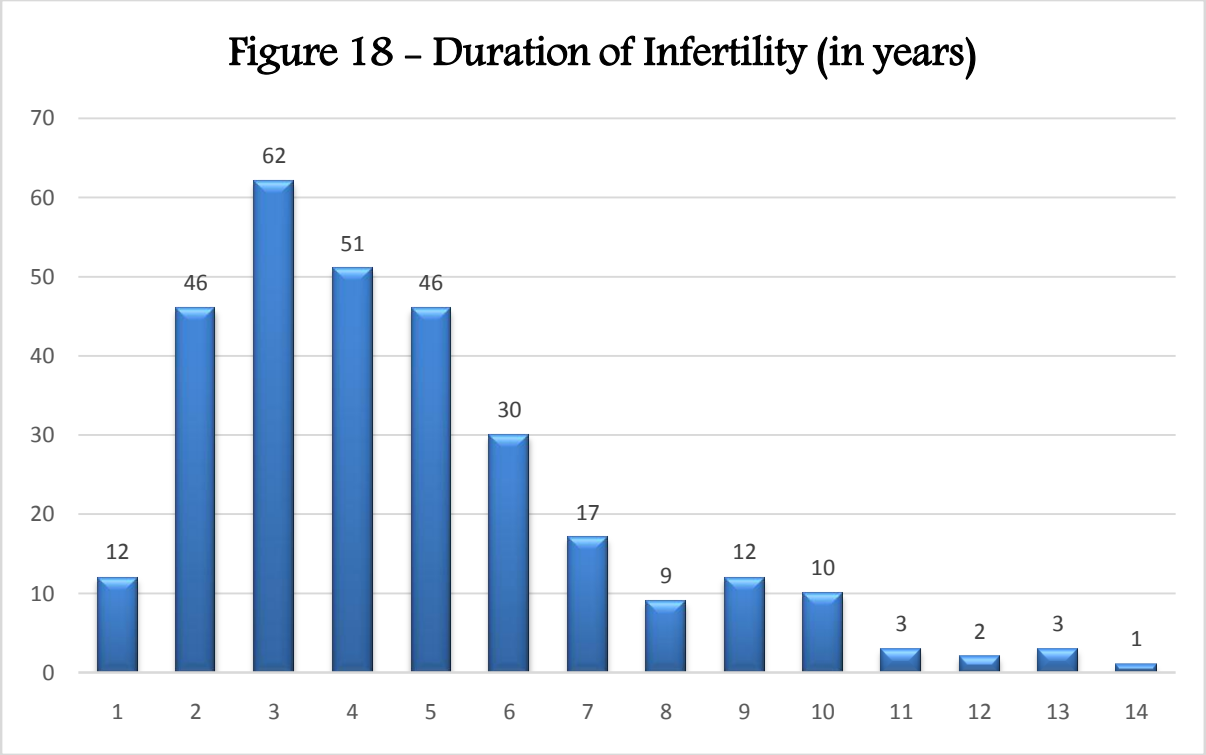
there was an increase in the age group of males aged less than 29 years from 1.8% reported in 2016 to 3.3% reported this year. It is also good to note that the youngest male undergoing IVF/ICSI procedure this year was only 25years.



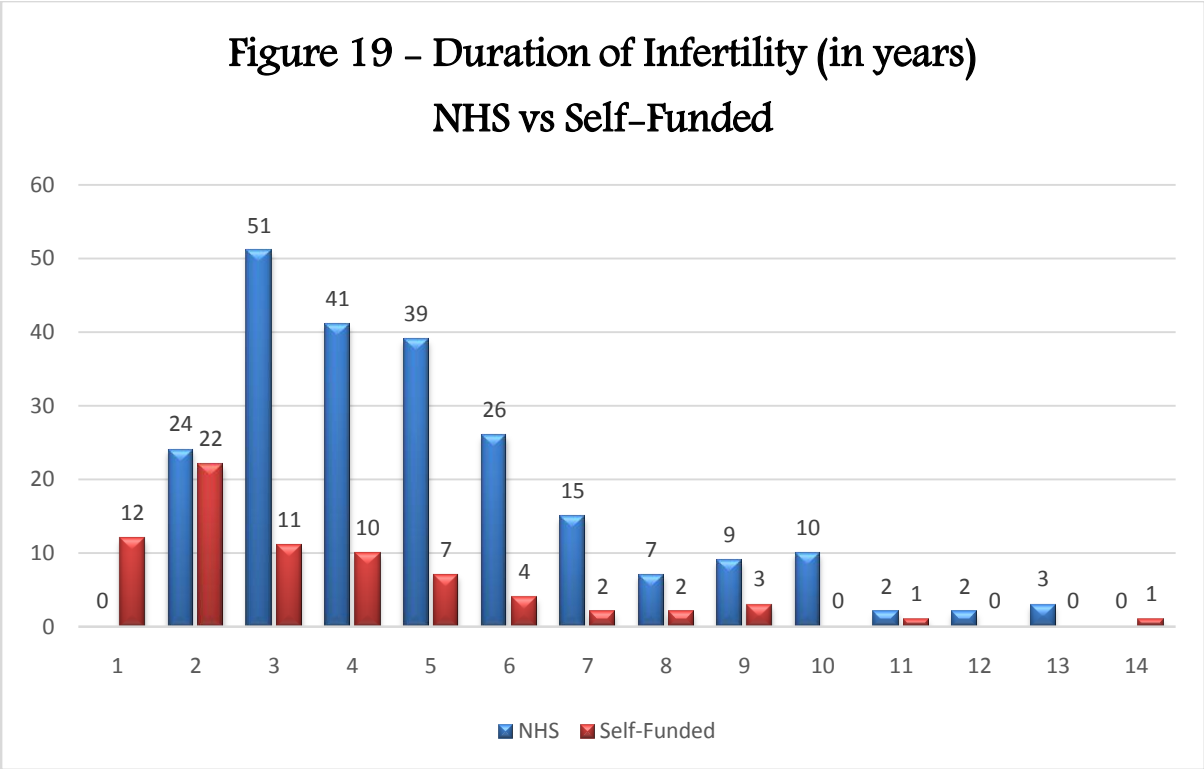
4. INFERTILITY

4.1. Duration of Infertility

There was a significant amount of variability in the reported duration of infertility amid couples undertaking procedures in 2017, with the minimum reported duration being that of one year, up to a maximum of 14 years. All the twelve (12) couples who reported to be infertile for one year only, had undergone treatment at the private sector and self-funded their treatment. Forty six (46) couples reported to be infertile for two years, sixty two (62) couples for 3 years, fifty one (51) couples for 4 years, forty six (46) couples for 5 years, while seventy eight (78) couples reported to be infertile between 6 and 10 years. Only nine 9 couples who had undergone treatment reported being infertile between 11 and 14 years. (Figure 18).



To be eligible for treatment on the NHS, a couple must declare being infertile for at least two years. In fact, 16% of couples who self-funded their treatment declared less than 2 years of infertility. The majority of couples (57.3%) self-funding their treatment have reportedly been infertile for 2 to 4 years, while the remaining 26.7% have been infertile for 5 years or more. Similarly, the majority of couples (50.7%) who applied to undergo IVF/ICSI treatment on the NHS declared being infertile for 2-4 years. Sixty five (65) couples, or 28.4%, have declared being infertile for 5-6 years, while the remaining forty eight (48) couples (20.9%) have been infertile for seven years or more (Figure 19).



Noteworthy is the fact that 155 couples (67.69%) of total couples undergoing treatment on the NHS reported to have been infertile for less than 5 years. This may be explained by the fact that since the service is now being offered for free by the Government, it is easier for couples to resort to IVF/ICSI earlier, at a younger age.

4.2. Classification of Infertility

IVF/ICSI procedures are offered free of charge by the Government to couples who have no children (Primary Infertility), or to those who have children from a previous relationship (Secondary Infertility). The majority of couples, 252 couples (82.89%) who have applied for IVF/ICSI treatment in both the NHS and private sector suffered from Primary Infertility (Table 1).

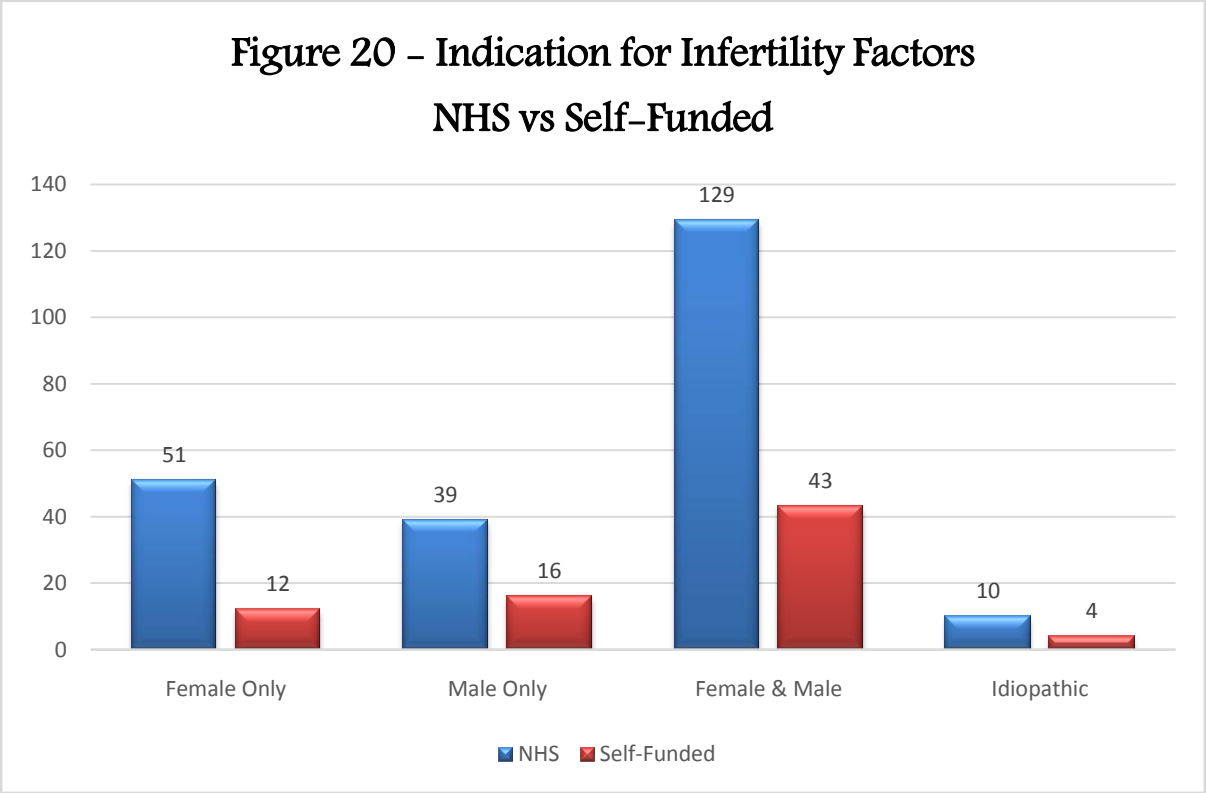
Table 1. Classification of Infertility

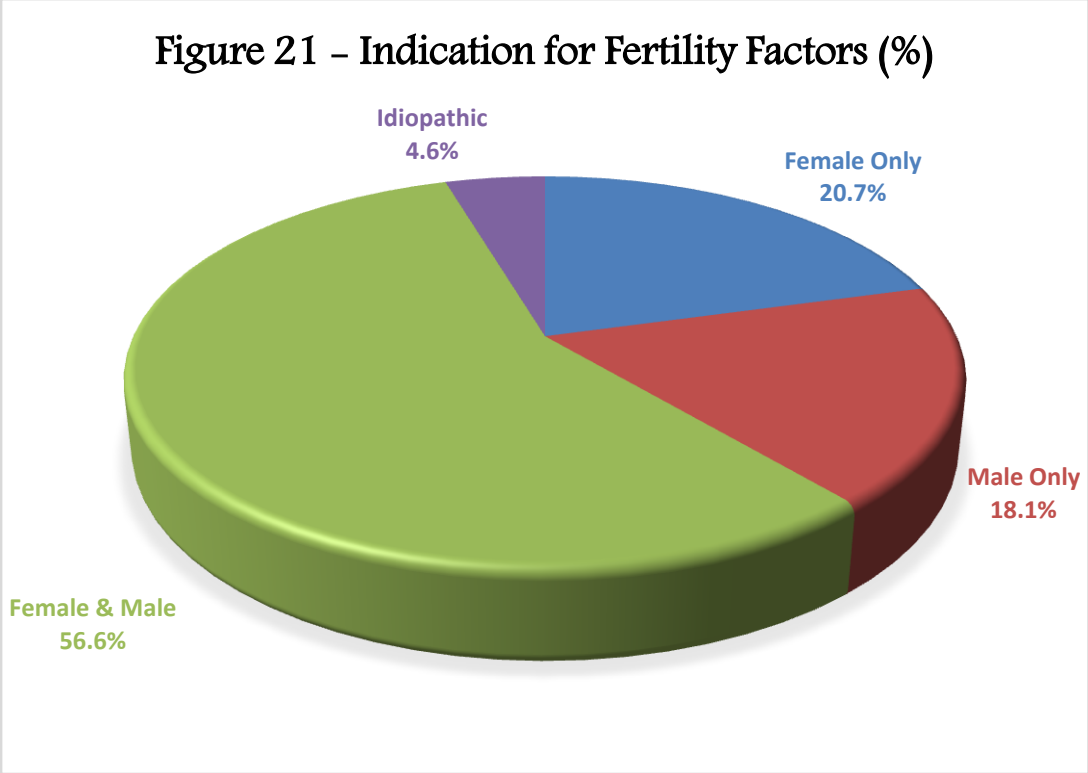
Classification of Infertility	NHS	Self-Funded	Total	%
Primary	201	51	252	82.89%
Secondary- Same Relationship	0	22	22	7.24%
Secondary- Previous Relationship-Female	17	1	18	5.92%
Secondary- Previous Relationship-Male	11	1	12	3.95%
Total	229	75	304	

4.3. Indication for Infertility Factors

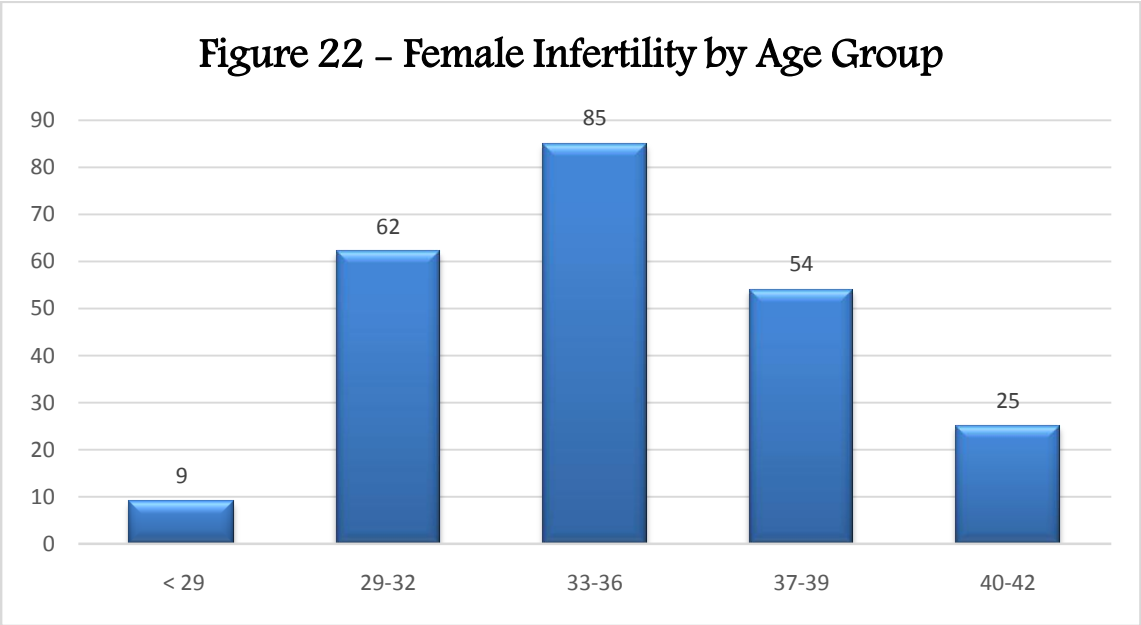
The Authority gathers data on what the contributing factor of infertility for each couple is. These consist of Female factor only, Male factor only, Female and Male factor, and Idiopathic (unexplained) infertility.

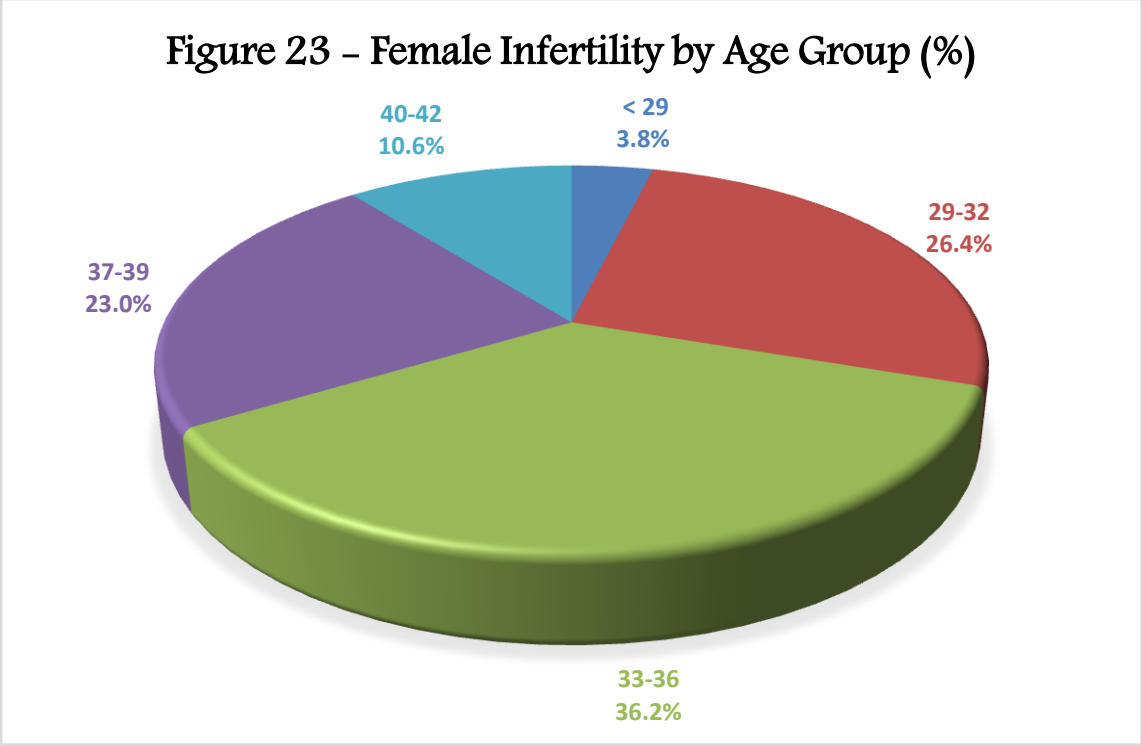
As shown in Figures 20 and 21, the majority of couples (56.6%) undertaking IVF/ICSI procedures suffered from Female and Male factor infertility. These were followed by couples (20.7%) suffering from Female factor only and very closely followed by the couples (18.1%) suffering from Male factor only while the remaining 4.6% suffered from idiopathic infertility. These figures are very much in line with those reported in 2016. A plausible explanation for this would be that fertility investigations are becoming more and more comprehensive and hence, the cause of infertility may be more easily resolved.



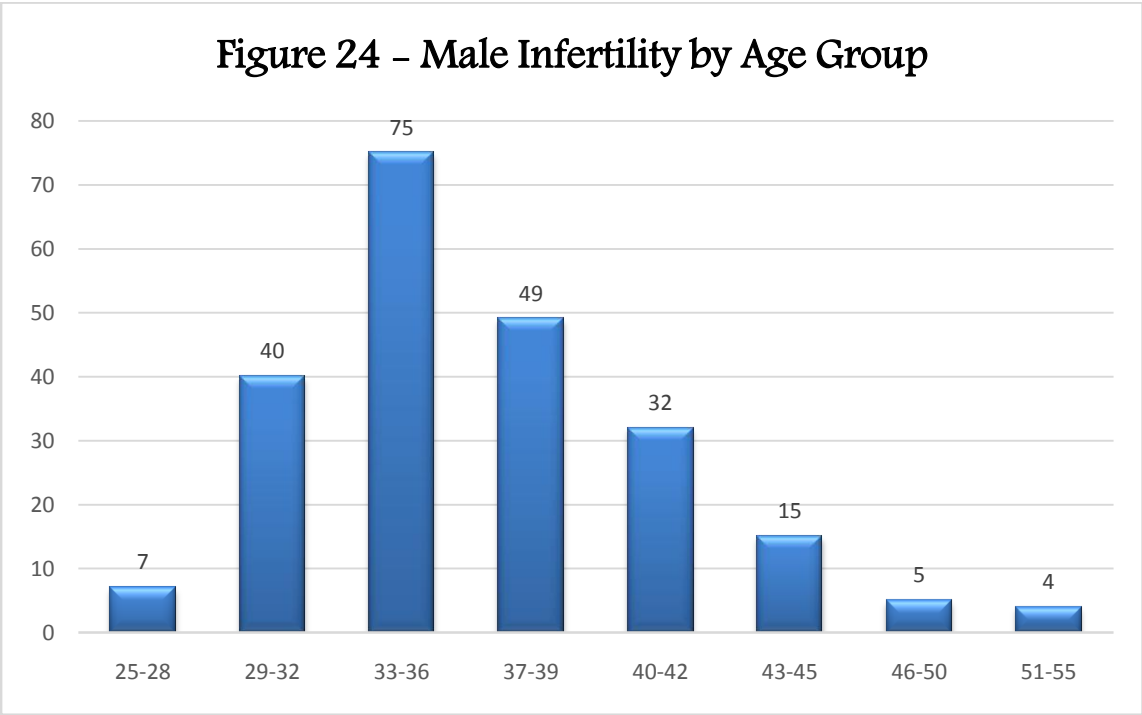


From those couples suffering from Female factor infertility only, the largest group (36.2%) were in the 33-36 year old bracket, this age bracket also registered an increase of 4.4% over figures reported in 2016. (Figures 22 and 23).





From those couples suffering from Male factor infertility only, the largest group (33%) were also reported in the 33-36 year old bracket, followed by males in the 37-39 year old bracket. (Figures 24 and 25).



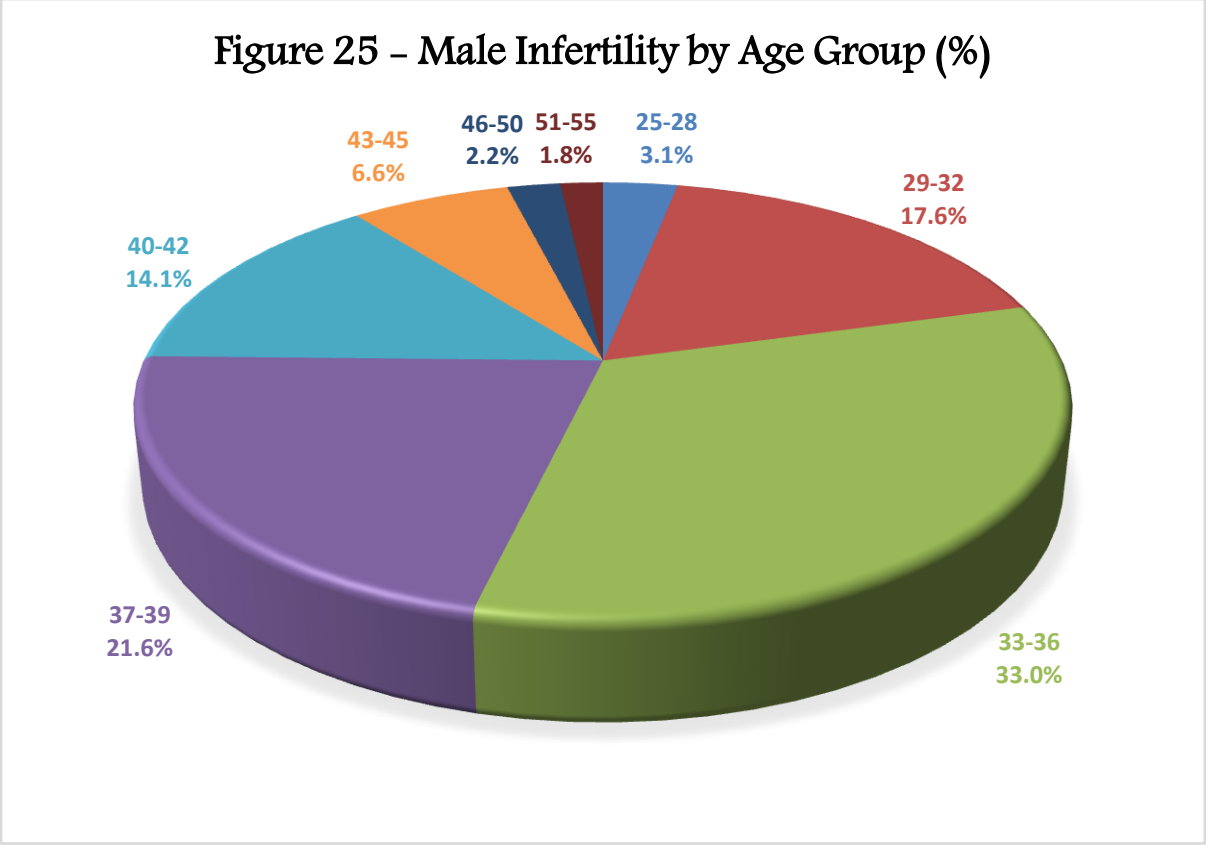


Figure 25 – Male Infertility by Age Group (%)
25-28
3.1%
29-32
17.6%
33-36
33.0%
37-39
21.6%
40-42
14.1%
43-45
6.6%
46-50
2.2%
51-55
1.8%

5. TYPE OF CYCLE

5.1. Fresh vs Thawed

Pursuant to the introduction of the Embryo Protection Act of 2012, the maximum number of oocytes which may be injected in any one cycle is two oocytes (or three oocytes in cases approved by the Authority). All embryos created will have to be transferred since vitrification (freezing) of embryos is forbidden by law. Thus, oocyte selection and vitrification are routine practice at the local ART clinics.

Couples may opt for Fresh or Thawed cycles, or a combination of Fresh and Thawed. Given that vitrification technology holds great promise in terms of gamete survival, pregnancy rates, and live births, data gathered on the outcomes from Thawed cycles is of high relevance. This is especially true in light of gamete vitrification techniques being employed for fertility preservation, like in the case of oncology patients.

From a total of 304 procedures carried out, 231 (75.99%) were Fresh cycles; while another 73 (24.01%) were Thawed cycles. None of the couples, in 2017, opted for a combined cycle whereby both fresh and thawed oocytes would have been utilized for the procedure.

Noteworthy is the fact that there has been a 5.29% increase in fresh cycles when compared to last year and a drop of 4.93% in the couples opting to

undergo a thawed cycle. The majority of cycles (80.79%) carried out at the ART Clinic in Mater Dei Hospital were Fresh cycles and only 19.21% were Thawed. In the self-funded cycles the majority of cycles (61.33%) were Fresh, and the remaining 38.67% were Thawed cycles (Table 2).

Table 2. Type of Cycle

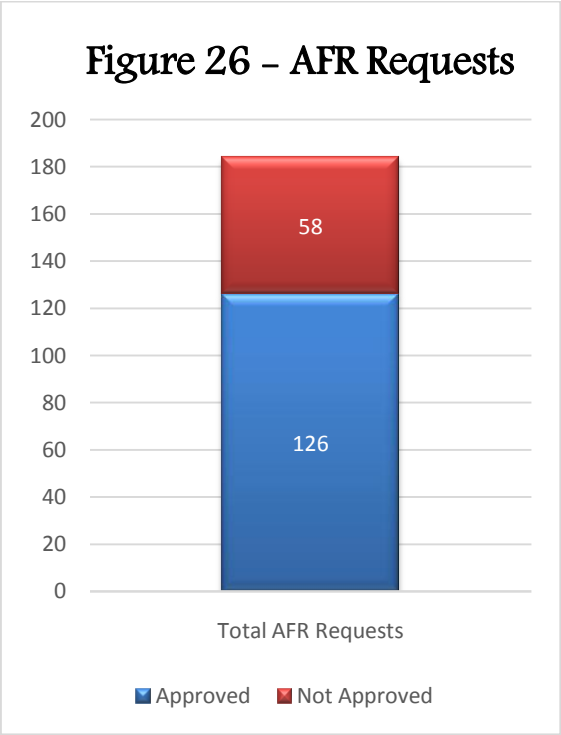
Fresh/Thawed	NHS	Self-Funded	Total	% of Total
Fresh	185	46	231	75.99%
Thawed	44	29	73	24.01%
Total	229	75	304	

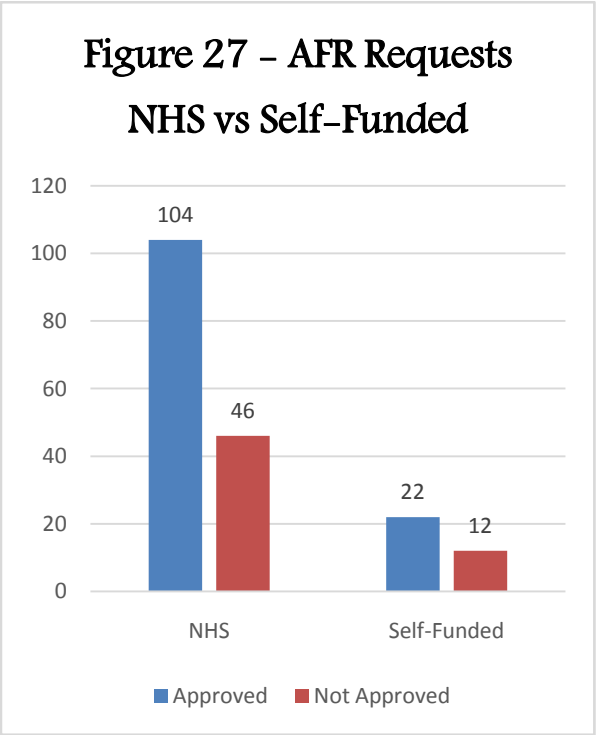
5.2. Additional Fertilization Requests (AFRs)

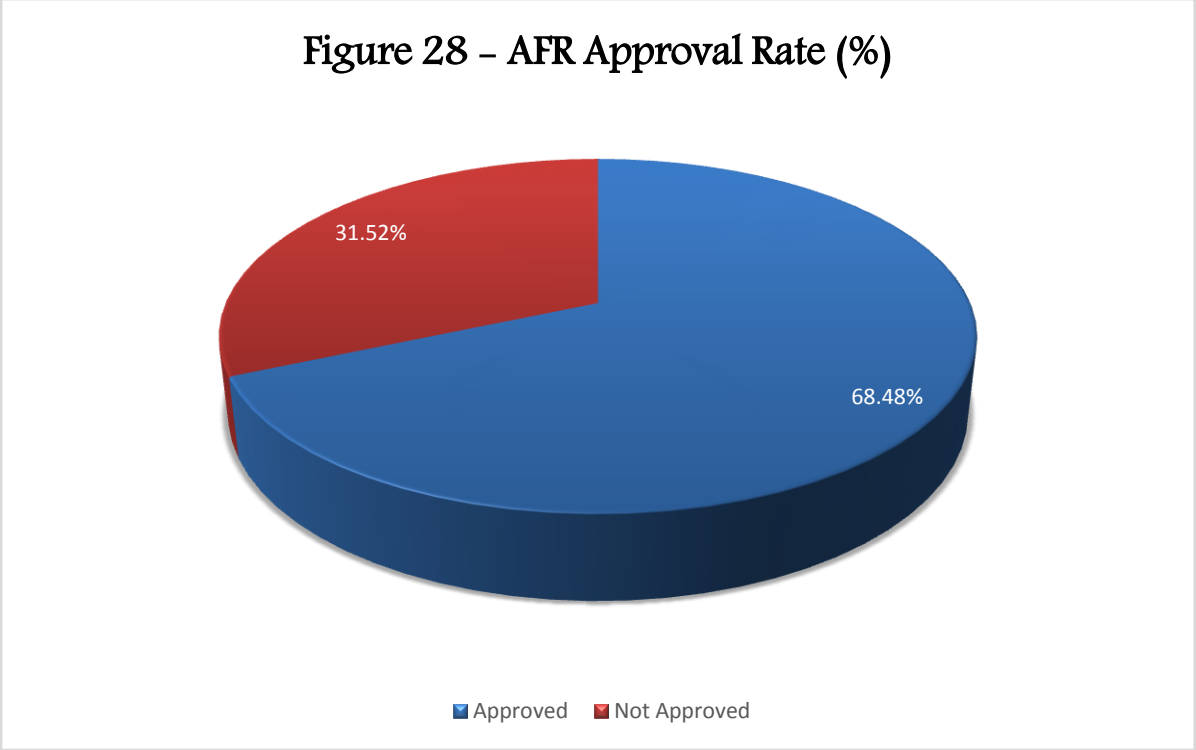
The Authority receives a significant number of requests from the licensed establishment clinicians to consider the fertilization of three oocytes for specific couples, instead of the two permitted by law. These requests are analysed and discussed between the Members of the Authority together with Representatives from the Obstetrics and Gynaecology Association and the Paediatric Association of Malta, as per Article 6 of the Embryo Protection Act. Requests are considered on a case by case basis and matched against established criteria. These criteria include the age of the female patient undergoing treatment, together with the number of failed IVF/ICSI cycles that the couple had already undergone.

Throughout 2017, a total of 184 requests were received by the Authority. The majority of requests, 150 requests (81.52%) came from the ART Clinic at MDH, where 46 requests (30.67%) of them were not approved.

In contrast, while the minority of requests, 34 requests only (18.48%) of the AFR requests were made by private clinics, 12 requests amounting to 35.29% have not been approved (Figures 26 and 27). Out of the total requests received, 68.48% were approved while the remaining 31.52% were not approved. (Figure28). The approval rate is 3.95% higher than the figures quoted in 2016.







During 2017, the Authority was notified by one of the couples undergoing treatment at MDH, that although the clinician had requested additional fertilisation and the Board had approved the request, the couple had decided that due to the wife being in the 40 – 42 year old bracket, they did not want to take the risk of three embryos being transferred. The couples request was approved by the Authority and the clinic was informed accordingly to fertilise only two oocytes.

6. GAMETES

6.1. Transfer of Gametes

Throughout 2017, there were 9 female patients who had their oocytes transferred from MDH to the licensed private Clinic. In turn, gametes of 4 patients, 2 females and 2 males, have been transferred from the private clinic to MDH. It appears that not all gametes have been transferred for immediate utilization.

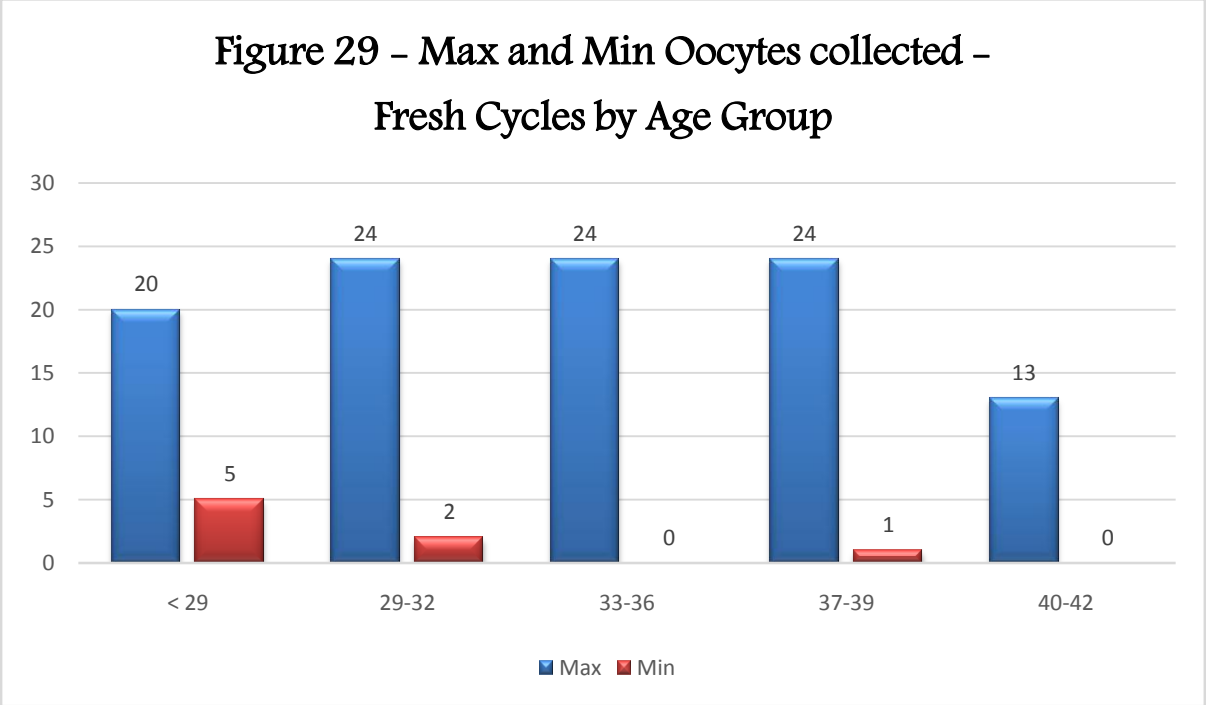
6.2. Collection of Oocytes

The number of oocytes a female has remaining for the future, better known as 'ovarian reserve' is closely related to a woman's age but can vary considerably at any age. Oocyte quality is also associated with female age and the better the quality, the higher the probability for pregnancy since embryo quality is dependent on the quality of the oocytes. The number of oocytes attained through ART procedures such as IVF/ICSI strongly influences the chance for success.

During a Long Protocol IVF cycle, the female patient goes through down-regulation and ovarian stimulation phases that prepare her for treatment. The purpose of the Ovarian Stimulation phase is to stimulate the ovary into producing several follicles, inducing a controlled ovulation and maturation of oocytes so as to increase the chances of achieving a pregnancy during treatment.

From the 231 Fresh cycles carried out in 2017, a total of 1946 oocytes have been collected, for an average of 8.42 oocytes per patient. The maximum

number of oocytes collected from a single patient was 24 oocytes. Three patients one aged 29 years, another aged 36 years and another aged 37 years, all had 24 oocytes each to collect, all patients had undergone treatment at MDH. Conversely, there were 3 patients, one aged 36 years and two patients aged 42 years, undergoing treatment at MDH who produced zero (0) oocytes. (Figure 29).



As expected, the largest number of oocytes collected, for an average of 12.08 oocyte per patient, was from females aged between 25 and 29, these were closely followed by 10.87 oocytes per patient, from females in the 29-32 year old bracket. An average of 8.74 oocytes was collected from patients aged 33-36. Not surprisingly, less oocytes were collected from women aged 37-39 and 40-42, for an average of 6.97 and 4.22 oocytes respectively (Table 3).

Table 3. Oocytes Collected by Age Group

Age	No of Females	Total Oocytes Collected	Average	Max	Min
< 29	12	145	12.08	20	5
29-32	45	489	10.87	24	2
33-36	92	804	8.74	24	0
37-39	59	411	6.97	24	1
40-42	23	97	4.22	13	0
OVERALL	231	1946	8.42		

When taking into account the number of oocytes collected from the total number of female patients undergoing a Fresh cycle, it would appear that the quantity of oocytes collected per cycle relative to the age of the female patient is higher at MDH in patients aged between 37 and 42. While in the self-funded cycles the quantity of oocytes collected per cycle relative to the age of the female is higher in patients between 25 and 36 years of age. (Table 4).

Table 4. Oocytes Collected by Age Group – NHS vs Self-Funded

	NHS			Self-Funded		
Age	No of Females	Total Oocytes Collected	Average	No of Females	Total Oocytes Collected	Average
< 29	7	83	11.86	5	62	12.40
29-32	32	349	10.91	13	140	10.77
33-36	81	699	8.63	11	105	9.55
37-39	48	363	7.56	11	48	4.36
40-42	17	72	4.24	6	25	4.17
OVERALL	185	1566	8.46	46	380	8.26

As pointed out already, women are born with a lifetime reserve of oocytes, and with age, the quantity and their quality gradually decrease. The cells in developing follicles secrete a chemical substance named Anti-Mullerian Hormone (AMH) and the levels of this particular hormone in a woman's blood, is normally a good indicator of her ovarian reserve. With increasing age, serum AMH levels decrease. Women suffering from polycystic ovaries tend to have high serum AMH concentrations while women close to menopause normally have low levels.

Clinicians generally refer to the AMH test results to get some insight into the remaining amount of oocytes their patient has got. This is especially important since low AMH values could possibly suggest a poor response to IVF, while high values may denote an over-response to the IVF medication. Unfortunately, AMH levels do not tell us much about the quality of a woman's oocytes or her ability to get pregnant.

An analysis of the quantity of oocytes collected for women aged 37 or under, and whose serum AMH values were $\leq 1\mu g/l$, was performed. To avoid distorted results from this analysis, an age and serum AMH values cut-off range were set based on the fact that women approaching menopause would normally have low AMH levels in any case.

Due to the fact that a significant number of AMH test results were older than 6 months, on the day of oocyte retrieval the actual serum AMH values of the patient might have been less than the reported value. Hence the accuracy of all the AMH-related analysis in this report cannot be guaranteed. The data in the

chart may however be of significance to clinicians dealing with patients with poor ovarian reserve, with respect to possibilities and expectations.

Througout 2017, there were 25 female patients aged 37 or under with a serum AMH concentration of ≤1μg/l, who had undergone a Fresh cycle. The total amount of oocytes collected from these 25 patients was 123, with the maximum number of oocytes collected being 17 and the minimum 0 (zero). The average number of oocytes collected was 4.92 per patient and there were 18 females who had 3 or more oocytes collected (Table 5).

Table 5. Oocytes collected for AMH ≤1μg/l (Age ≤37)

AMH <= 1 Occurances	Min Oocytes Collected	Max Oocytes Collected	Total Oocytes Collected	Average Oocytes Collected	Occurances with 3 oocytes or more
25	0	17	123	4.92	18

6.3. Oocytes Discarded

Oocytes obtained following ovarian stimulation should meet certain criteria in order to be considered suitable for IVF/ICSI. An appraisal is usually done by Embryologists to classify these oocytes, and those which are not deemed suitable for immediate fertilization or vitrification are discarded.

A total of 995 oocytes have been discarded in 2017. Seven hundred and ninety (790) oocytes (79.40% of all discarded oocytes), or 40.60% from the total oocytes collected, were discarded following the egg retrieval process (Fresh cycle), for an average of 3.42 discarded oocytes per Fresh cycle. The remaining 205 oocytes (20.60% of all discarded oocytes) failed to survive the thawing process, for an average of 2.81 oocytes discarded per Thawed cycle (Table 6).

Table 6. Oocytes Discarded

Age	No of Females (Fresh Cycle)	Total Oocytes Discarded (Fresh Cycle)	Average Oocytes Discarded (Fresh Cycle)	No of Females (Thawed Cycles)	Total Oocytes Discarded (Thawed Cycles)	Average Oocytes Discarded (Thawed Cycles)	No of Females (Overall)	Total Oocytes Discarded (Overall)	Average Oocytes Discarded (Overall)
< 29	12	57	4.75	2	8	4.00	14	65	4.64
29-32	45	202	4.49	30	99	3.30	75	301	4.01
33-36	92	343	3.73	22	56	2.55	114	399	3.50
37-39	59	163	2.76	13	31	2.38	72	194	2.69
40-42	23	25	1.09	6	11	1.83	29	36	1.24
OVERALL	231	790	3.42	73	205	2.81	304	995	3.27

Unlike 2015 and 2016, where the largest number of oocytes discarded was reported to be from women in the 29-32 year old bracket, in 2017 the largest number of oocytes discarded is from women in the 33-36 year old bracket which incidentally was the group from which the largest number of oocytes had been collected (Figures 30 and 31).

Figure 30 – Average Oocytes Discarded by Age Group (Fresh vs Thawed)

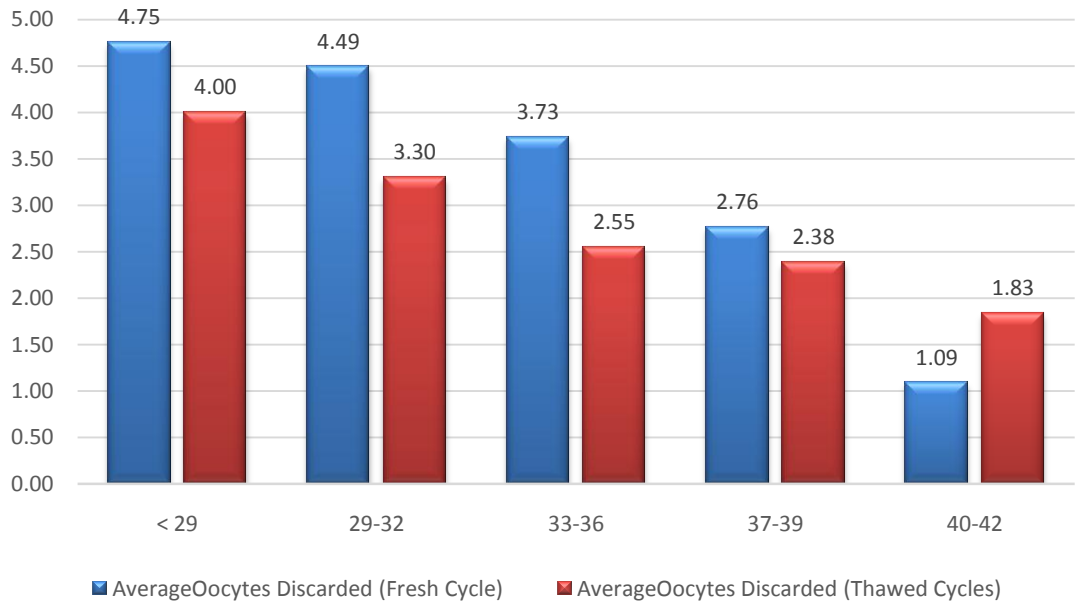
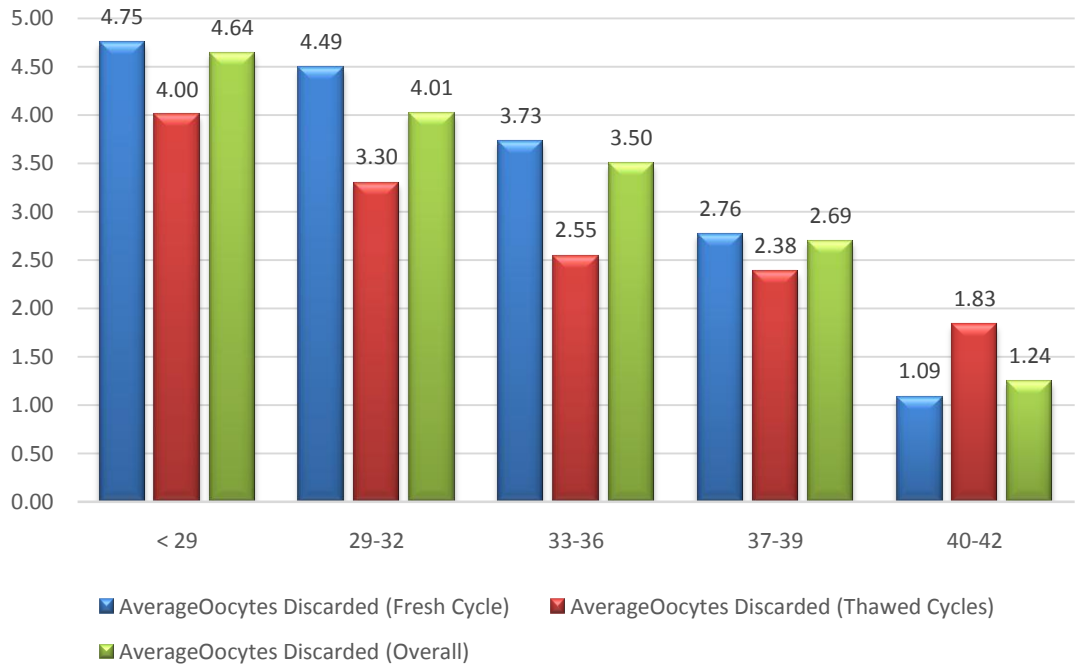


Figure 31 – Average Oocytes Discarded by Age Group (Fresh vs Thawed vs Overall)



6.4. Fresh vs Thawed Sperm

Out of the 304 cycles carried out last year, thawed sperm has been utilized in 3 cycles only, or 0.99%, of the IVF/ICSI procedures undergone. Fresh sperm, ejaculated or in some instances obtained through testicular extraction/aspiration, has been used in the remaining IVF/ICSI procedures which have been carried out.

6.5. Storage of Gametes

Pursuant to the introduction of the Embryo Protection Act of 2012, licensed clinics were allowed to store gametes (oocytes and sperm). Storage of gametes started as of July 2013 in the private licensed clinic, while storage from Government-funded cycles started in January 2014. Storage at the MDH facility started as of January 2015.

6.5.1. Storage of Oocytes

Out of the 231 couples who had oocytes retrieved, only 112 (48.48%) had enough oocytes to store. A total of 119 couples had no oocytes left to vitrify (Table 7). This is in contrast to figures registered in 2016 where more couples had oocytes to store than couples who had oocytes to discard.

Table 7 – Fresh Cycles with NO Oocyte Vitrification

	NHS			Self-Funded			Total		
Age	No of Cycles	Total Cycles with NO Oocytes to Vitrify	% of cycles with no Oocytes to Vitrify	No of Cycles	Total Cycles with NO Oocytes to Vitrify	% of cycles with no Oocytes to Vitrify	No of Cycles	Total Cycles with NO Oocytes to Vitrify	% of cycles with no Oocytes to Vitrify
< 29	7	2	28.6%	5	1	20.0%	12	3	25.0%
29-32	32	9	28.1%	13	3	23.1%	45	12	26.7%
33-36	81	44	54.3%	11	3	27.3%	92	47	51.1%
37-39	48	32	66.7%	11	6	54.5%	59	38	64.4%
40-42	17	14	82.4%	6	5	83.3%	23	19	82.6%
OVERALL	185	101	54.6%	46	18	39.1%	231	119	51.5%

The total number of oocytes vitrified from Fresh cycles carried out in 2017 was 696, for an average of 5.85 oocytes per couple. The maximum number of oocytes vitrified from a single cycle was 16.

The maximum number of oocytes thawed from Frozen cycles was 10, while the minimum number of oocytes thawed was 1.

6.5.2. Storage of Sperm

There has been a continuous request for sperm storage throughout 2017. A total of 58 patients, 53 at MDH and 5 at the private clinic, vitrified their sperm. In a number of cases, sperm was obtained through testicular aspiration/extraction (TESA/TESE).

Fertility preservation following oncology or urology referrals was the main reason these male patients had their sperm vitrified. Thirty four (34) of the male patients who stored their sperm proceeded with an IVF/ICSI cycle in the same calendar year, but only 3 of them used thawed sperm for the procedures (Table 8).

Table 8 – Storage of Sperm

Sperm Type	NHS	Self-Funded	Total	%
Vitrified	34	0	34	11.18%
Not Vitrified	195	75	270	88.82%
Total	229	75	304	

All the male patients that vitrified their sperm and proceeded to undergo an IVF/ICSI procedure were all undergoing their cycle at MDH (Figure 32). Out of all the procedures carried out it only accounts to 11.18% of all cycles, the remaining 270 males (88.82%) did not vitrify any sperm (Figure 33).

Figure 32 – Vitrified vs Non-Vitrified Sperm (NHS vs Self-Funded)

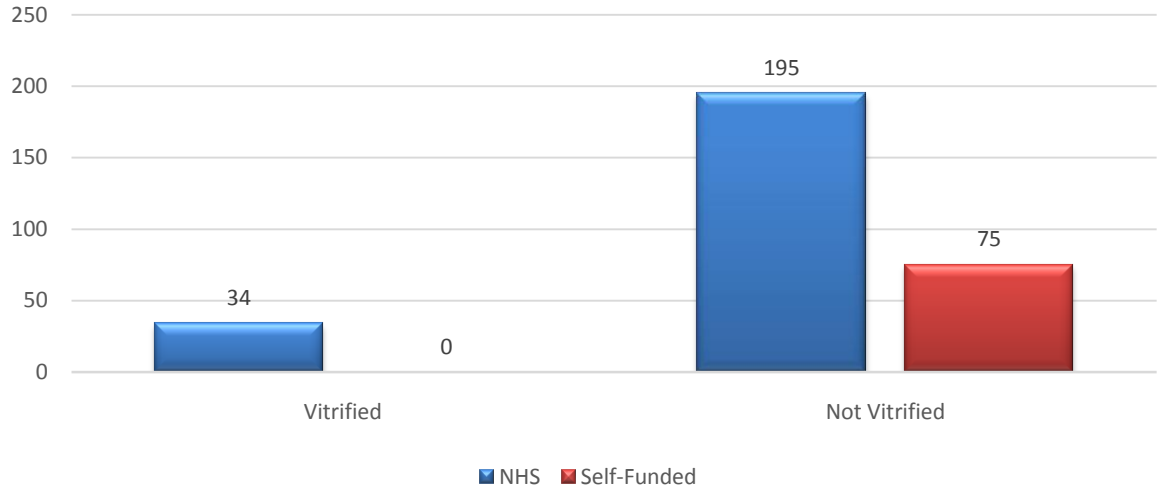
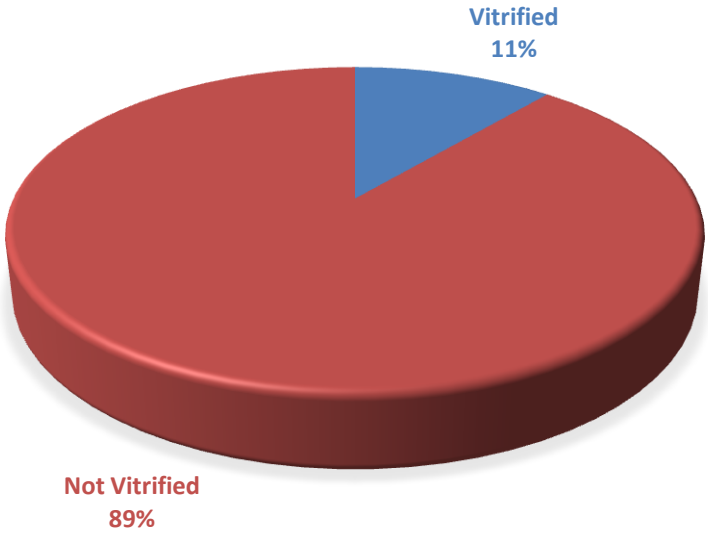


Figure 33 – Vitrified vs Non-Vitrified Sperm (% of All Cases)



6.5.3. 'Freeze-All' Cycles

In exceptional circumstances, clinicians may decide to proceed with oocyte retrieval but freeze all the oocytes for later fertilization. This is usually the case when uterine pathologies or a risk of Ovarian Hyperstimulation (OHSS) has been identified. It may also be the case that while the oocytes were being retrieved, the male partner had no viable sperm in the sample provided; or else no sperm was found during a TESA procedure, and hence fertilization couldn't take place. During this calendar year there were also patients who were given prior approval by the Authority to proceed with a freeze-all cycle, as per detailed in Section 1.9 above.

In 2017, the Authority was notified that there were 2 patients undergoing cycles at MDH who had a 'freeze-all' cycle, while at the private clinic there were 3 patients who had a 'freeze-all' cycles. Thus a total of 5 patients did not proceed with the fertilization process.

6.5.4. Embryo Freezing

In Malta, permission for vitrification of embryos can only be granted by the Embryo Protection Authority as per Article 7 of the Law, in the event that transfer of the fertilized embryos in the womb is not possible owing to grave and certified *force majeur* not predicted at the moment of fertilization. In 2017, no requests were made by the licensed clinics for vitrification of embryos. The only two embryos vitrified in 2016, are at the ART Clinic in MDH, and at the time of publication, were still in storage.

6.6. End of Storage

Last year no requests were received by the Authority from patients to have their gametes discarded.

6.7. Total Storage

As at 31st December 2017, the total amount of oocytes stored at the licenced clinics stood at a total of 1342 oocytes with the majority stored at MDH, whilst the total number of sperm vials was of 611, again the majority stored at MDH. The only two embryos vitrified are stored at the ART Clinic in Mater Dei Hospital (Table 9).

Table 9 – Total Storage

Type of Storage	NHS	Self-Funded	Total
Oocytes	906	436	1342
Sperm	528	83	611
Embryos	2	0	2

7. IVF/ICSI PROCEDURES

7.1. Cycles Started

In addition to the 304 cycles which have been performed throughout the year, licensed clinics have also reported a total of 33 cycles which were abandoned prior to oocyte retrieval. Twenty two (22) couples abandoned their cycle at the ART Clinic in MDH, while another eleven couples (11) who were going to self-fund their treatment abandoned their cycle. The majority of cycles were abandoned due to poor response to the stimulation treatment the female patients received. Other couples abandoned their cycle on medical grounds.

Noteworthy to note is that one couple reported abandoning the cycle due to financial matters as they could not meet up with the expense of the cycle.

7.2. Type of Procedure – IVF vs ICSI

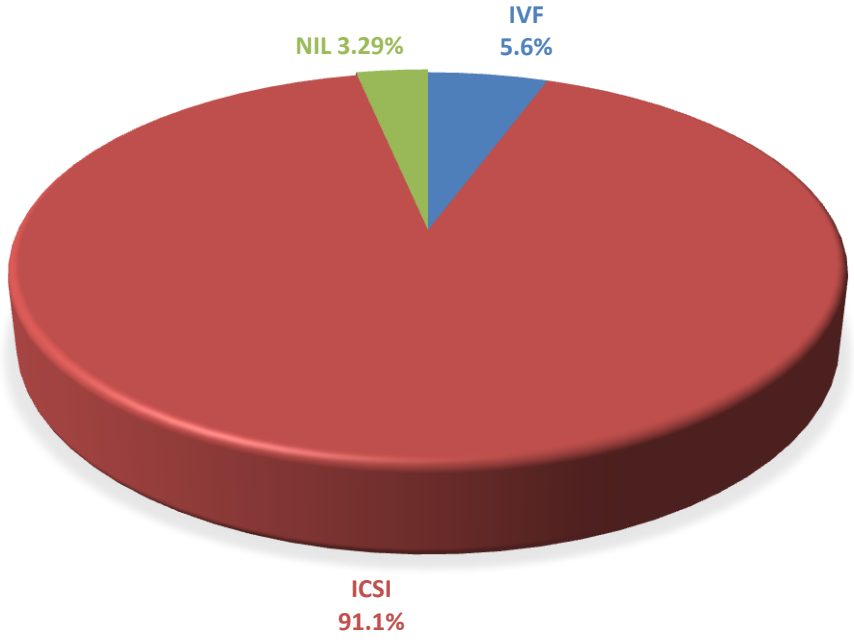
In 2017, from a total of 304 cycles started, no procedure was carried out for 10 couples. This was due to the fact that there were 3 couples who had no oocytes retrieved, another couple who had oocytes collected but which had to be discarded as they were of poor quality, another couple who had oocytes thawed but which had to be discarded as they were not viable, while the remaining 5 couples had to opt for a 'Freeze-all' cycle (Table 10).

Table 10. Type of ART Procedure

Type of ART	NHS	Self-Funded	Total	Total %
IVF	17	0	17	5.59%
ICSI	205	72	277	91.12%
NIL	7	3	10	3.29%
Total	229	75	304	

Out of the 294 procedures carried out, 277 or (91.12%), were *intra-cytoplasmic sperm injection* (ICSI). In contrast to conventional *in vitro* fertilization (IVF), where a single egg is incubated in the presence of a significant number of sperm, in ICSI, the embryologist selects a single sperm to be injected directly into an egg (Figure 34).

Figure 34 – IVF vs ICSI (% of Procedures) – Overall



Only seventeen out of the 222 procedures carried out at MDH were IVF, while the licensed private clinic opted for an '*All-ICSI*' approach (Figures 35 and 36).

Figure 35 – IVF vs ICSI (% of Procedures) – NHS

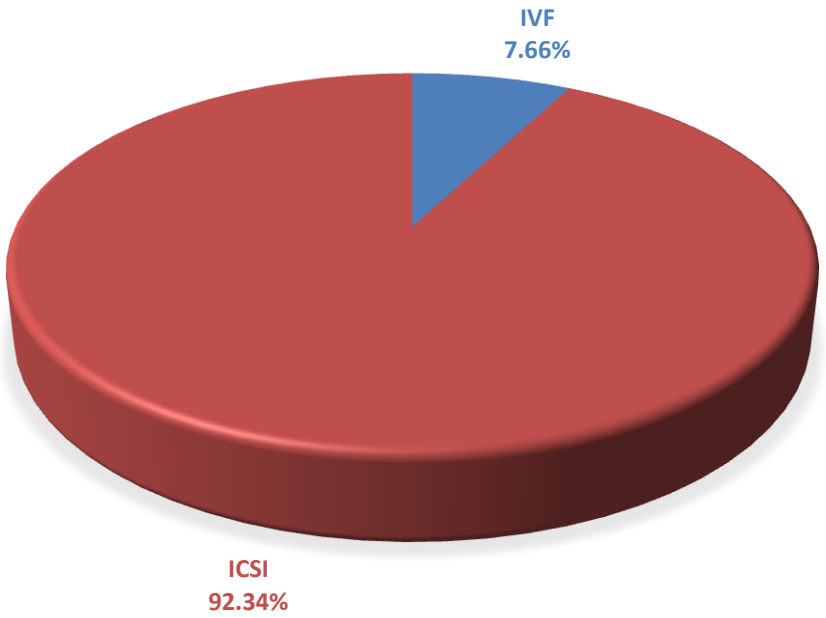
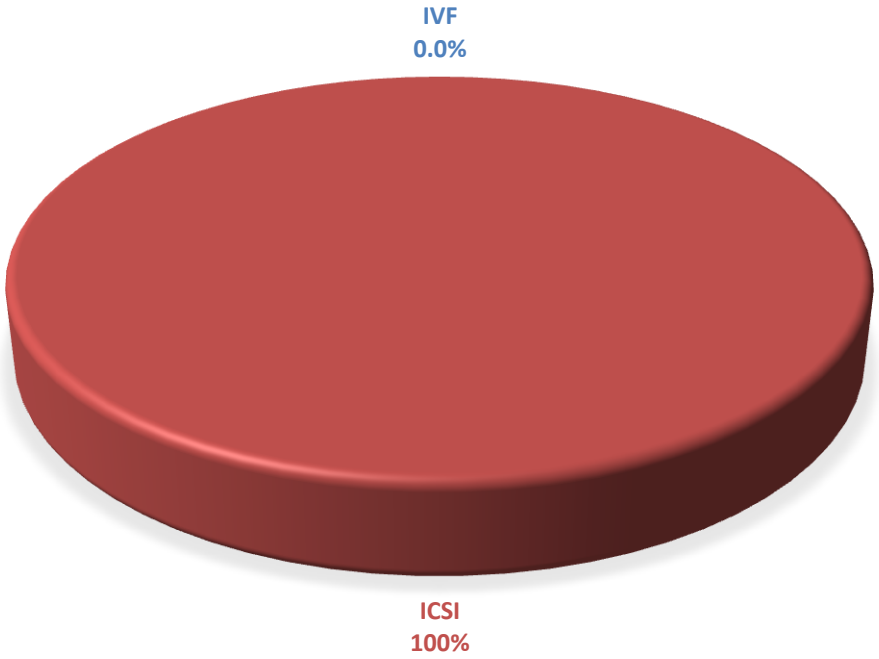


Figure 36 – IVF vs ICSI (% oF Procedures) – Self-Funded



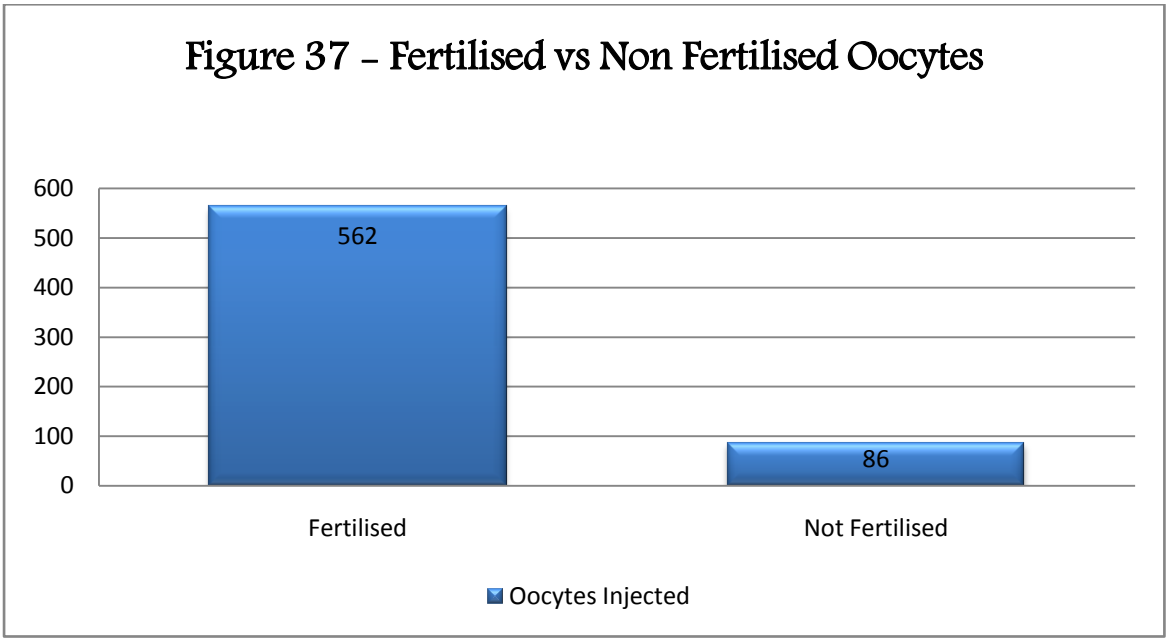
7.3. Oocytes Injected and Fertilisation

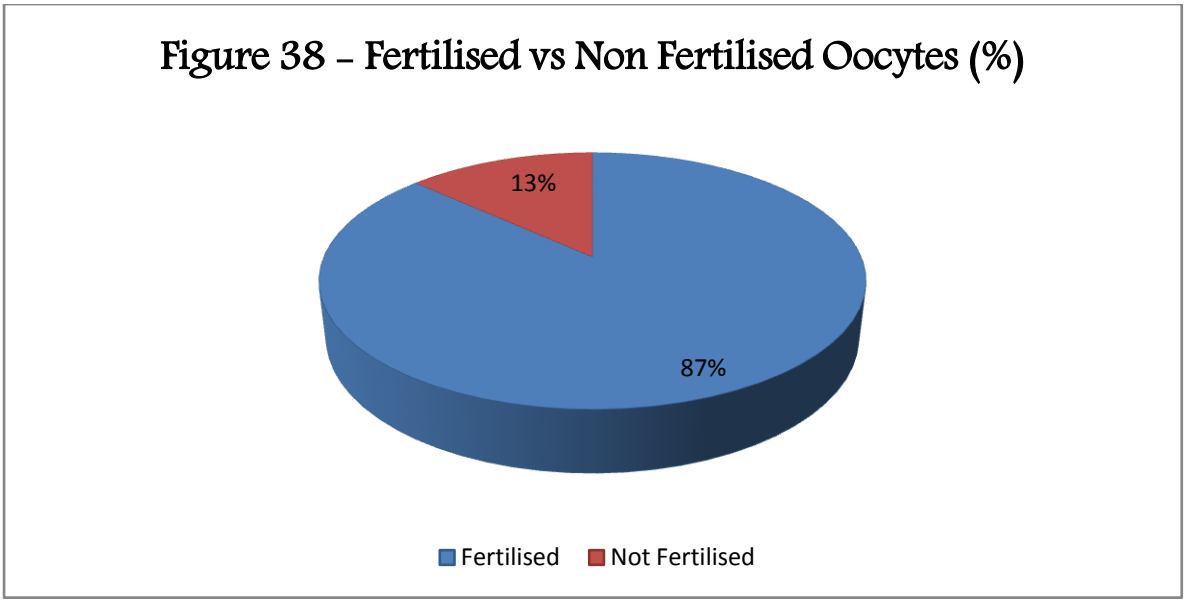
Throught 2017, a total of 648 oocytes were injected, the majority 493 oocytes or 76.08% of the total oocytes injected were from fresh cycles, the remaining 155 oocytes or 23.92% of the total injected oocytes where from thawed cycles (Table 11).

Table 11. Oocytes Injected

Type of Cycle	Oocytes Injected	%
Fresh	493	76.08%
Thawed	155	23.92%
Total	648	

Out of the total 648 injected oocytes, there were 562 oocytes that reached fertilisation stage while 86 oocytes did not fertilise (Figure 37). Thus fertilisation rate is of 86.73% of all oocytes injected (Figure 38).





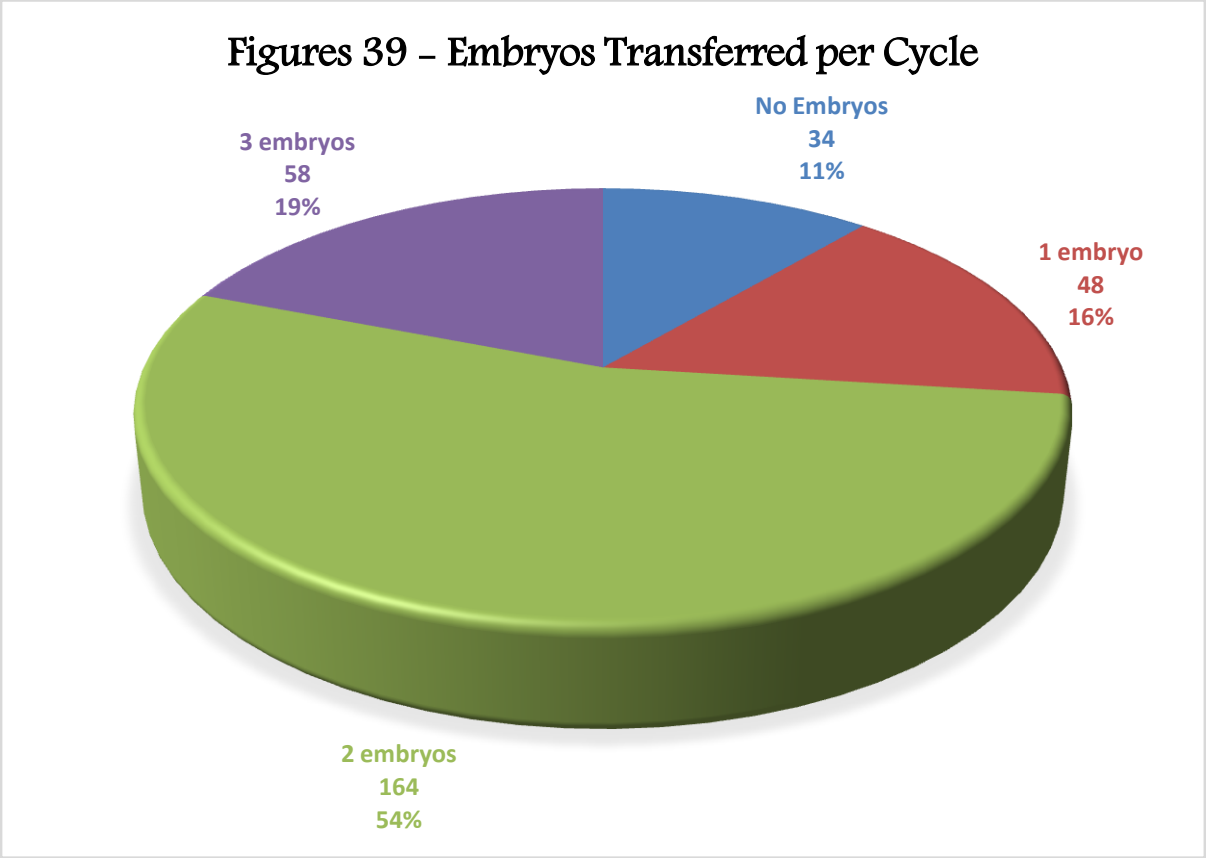
Out of the 562 fertilised oocytes, embryologists report that 12 oocytes had arrested during the incubation phase, 7 of these oocytes were from fresh cycles whilst 5 arrested oocytes were from thawed cycles. Thus resulting in only 550 embryos which were eventually transferred.

7.4. Embryo Transfers

Out of the 304 cycles carried out, 550 embryos were transferred. There were a total of 34 couples who had no Embryo Transfer effected. As outlined earlier, there were 10 couples, or 3.29%, who for various reasons had no IVF/ICSI procedures performed. The other 24 couples (7.89%) had no embryos to transfer as the oocytes they had injected failed to fertilize.

Out of the 270 couples who had viable embryos to transfer, 48 of them (15.79%) had a single embryo transferred. One hundred and sixty four

(53.95%) couples, had 2 embryos transferred, while the remaining 58 couples, or 19.08%, had 3 embryos transferred (Figure 39).

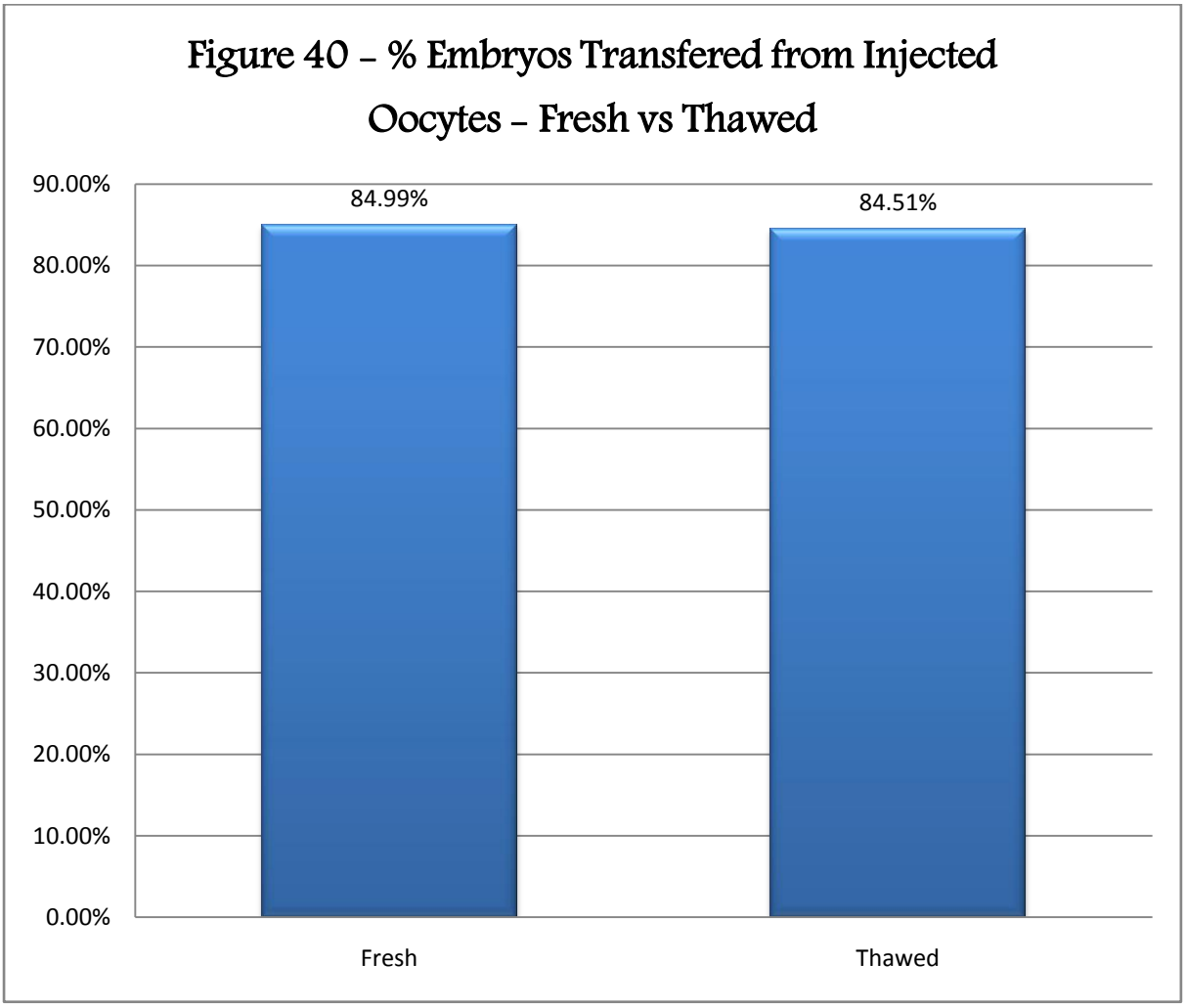


7.5. Embryo Transfers per Type of Cycle

Out of the 493 fresh oocytes injected, 419 (84.99%) resulting embryos were transferred and 144 embryos, or (84.51%), out of the 155 thawed oocytes injected have been transferred. This contrasts well with the figures reported in 2016, as there is a drop of 6.92% in embryos resulting from fresh oocytes injected. The embryos resulting from thawed injected oocytes registered an increase of 5.39% over last year. (Table 12 and Figure 40).

Table 12. Embryos Transferred per Type of Cycle (%)

Type of Cycle	Oocytes Injected	Embryos Transferred	Transferred %
Fresh	493	419	84.99%
Thawed	155	131	84.51%
Total	648	550	



7.6. Embryos Transferred per Approved AFR

Out of a total of 126 couples who had their Additional Fertilization Request (AFR) approved, all had an IVF/ICSI procedure carried out. Only 46.03% of these 126 couples had three embryos transferred despite having approval for the fertilization of a third oocyte (Figures 41 and 42).

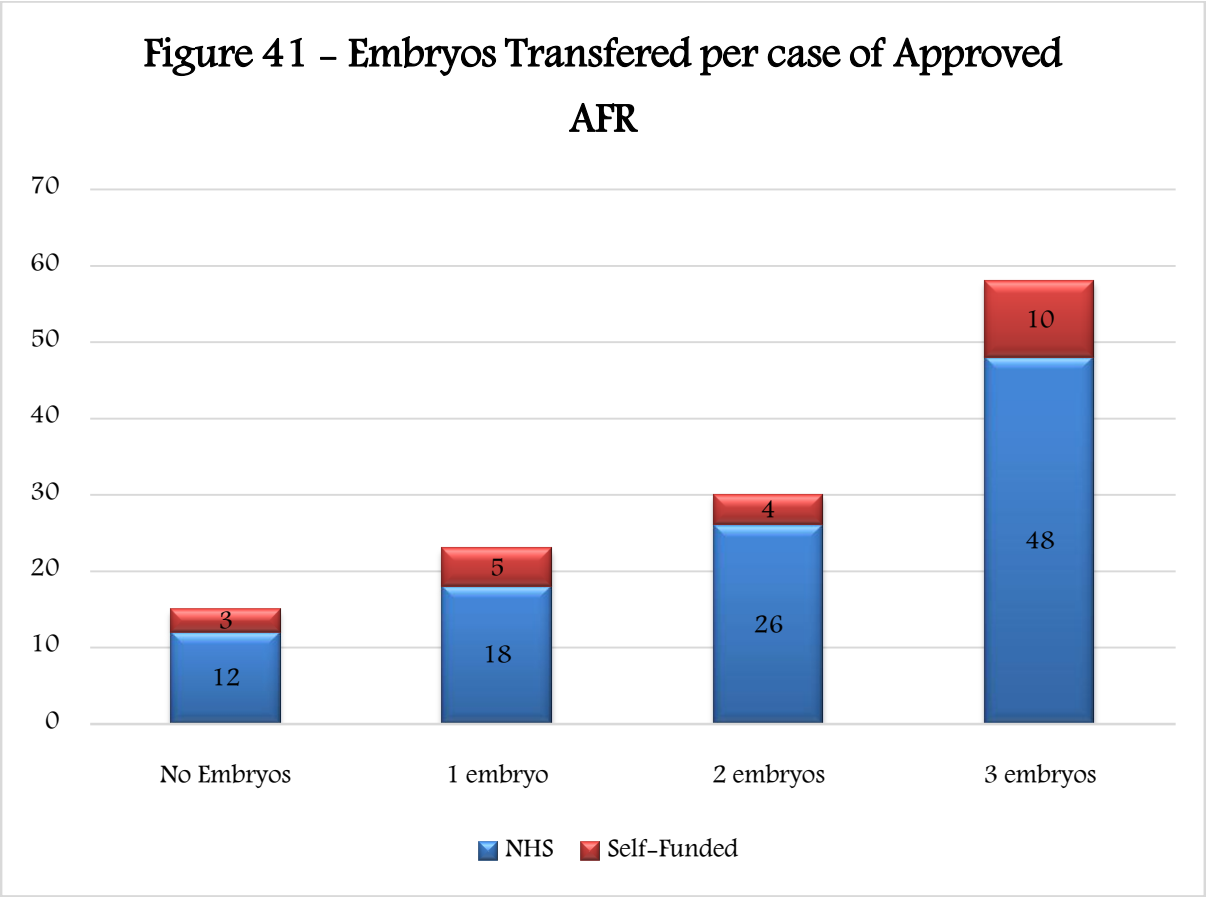
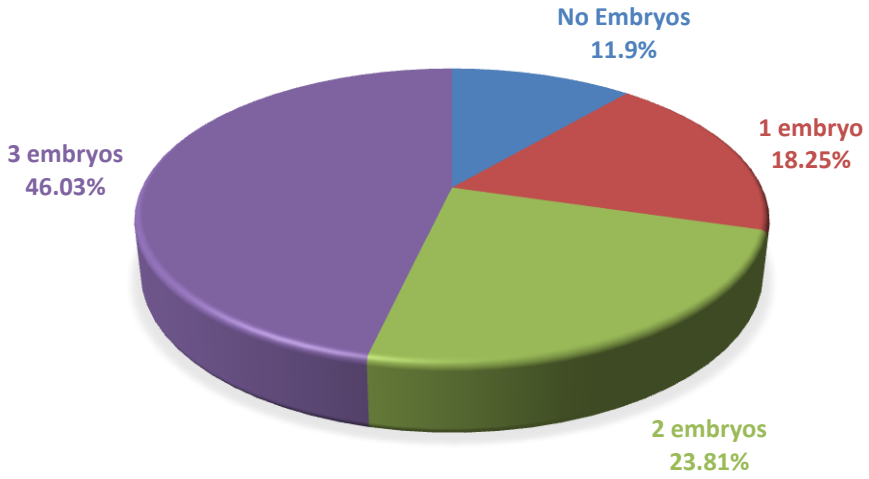


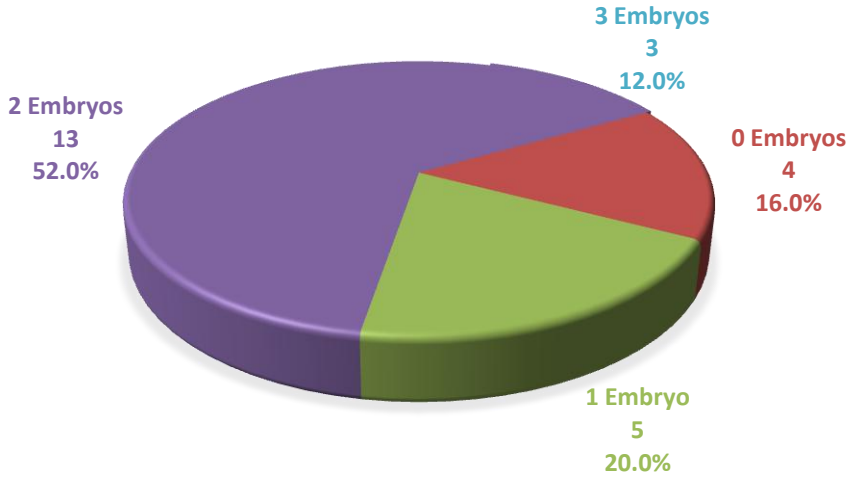
Figure 42 – Embryos Transfer Distribution (% of approved AFR)



7.7. Embryos transferred per AMH ≤1µg/l

As outlined already in Section 6.2., there was a total of 25 women aged 37 or under, with a serum AMH concentration of ≤1µg/l. Only 21 of these women had an embryo transfer affected as four women (16%) did not have any embryos to transfer. Five women, or 20%, had a single embryo transfer; 13, or 52%, had 2 embryos transferred, while the remaining three couples had 3 embryos transferred (Figure 43).

Figure 43 – Embryos Transferred for AMH ≤ 1ug/L (Age ≤37)



8. CYCLE OUTCOMES

In 2017, for two cycles that had resulted in a multiple pregnancy, one with triplets and one with twins, the women, a 36 year old and a 30 year old respectively, miscarried one of the embryos around gestational week 12 and week 9 respectively, but went on to deliver the other babies. In view of the fact that for the purpose of this report each ART cycle is considered as a single event based on its final outcome, as a result, the outcome from these particular cycles was that of a twin birth and a single birth. Hence, for statistical purposes, these cases are being reported as a Live Birth event. As a consequence, the miscarriages are not being accounted for in the relative tables and figures.

8.1. Pregnancies

Out of the 304 cycles carried out in 2017, there were 57 reported pregnancies from Fresh cycles and 9 from Thawed cycles. **The resulting 66 pregnancies account for 21.71% of all cycles started**, which is 1.73% less than the pregnancy rate for 2016 (Table 13).

Table 13. Cycle Outcome

Type	Outcome	NHS	Self-Funded	Total	% Outcome by Type	% Outcome	% Outcome of Pregnancies
Fresh	Not Pregnant	142	32	174	75.3%	75.3%	
Fresh	Miscarriage	7	3	10	4.3%	24.7%	17.5%
Fresh	Live Birth	8	8	16	6.9%		28.1%
Fresh	Expected	28	3	31	13.4%		54.4%
Thawed	Not Pregnant	38	26	64	87.7%	87.7%	
Thawed	Miscarriage	2	0	2	2.7%	12.3%	22.2%
Thawed	Live Birth	3	3	6	8.2%		66.7%
Thawed	Expected	1	0	1	1.4%		11.1%

8.2. Cycle Outcomes – Fresh vs Thawed

Fifty seven (57) couples, or 24.7% of those undergoing Fresh cycles managed to get pregnant. Out of these 57 pregnancies, 10 couples miscarried, 16 had a live birth, while the remaining 31 couples (13.4%) are still expecting (Figures 44 and 45). Nine (9) couples, or 12.3% of those undergoing a Thawed cycle got pregnant. Out of these nine pregnancies, 2 miscarried, 6 had a live birth, while the remaining 1 couple is still expecting (Figures 46 and 47).

As a result, in 2017 the pregnancy rate for Fresh cycles was 12.4% higher than for Thawed Cycles (Table 13). This increase is also due to the fact that the pregnancies from thawed cycles, in 2017 resulted in a drop of 9.2% in pregnancies when compared to thawed cycles registered in 2016.

Figure 44 – Outcome from Fresh Cycles

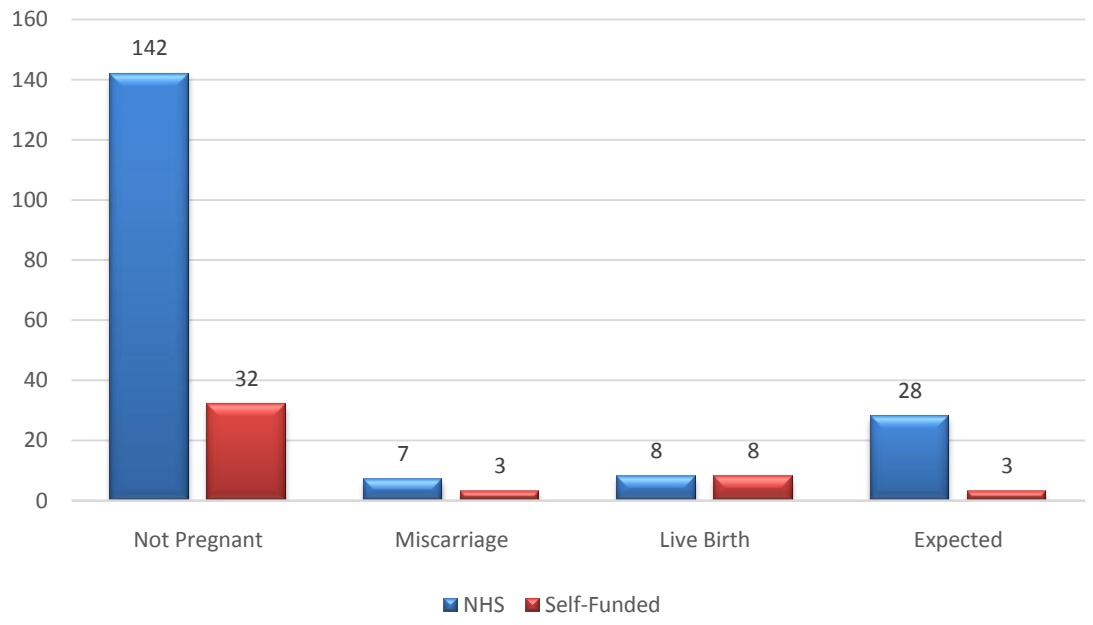
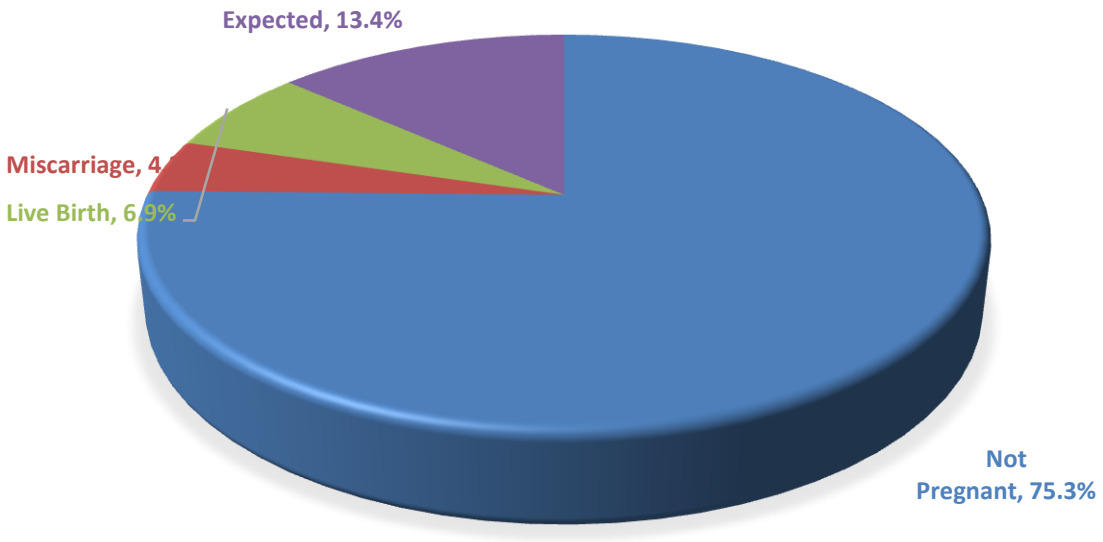


Figure 45 – % Outcome from Fresh Cycles (NHS + Self-Funded)



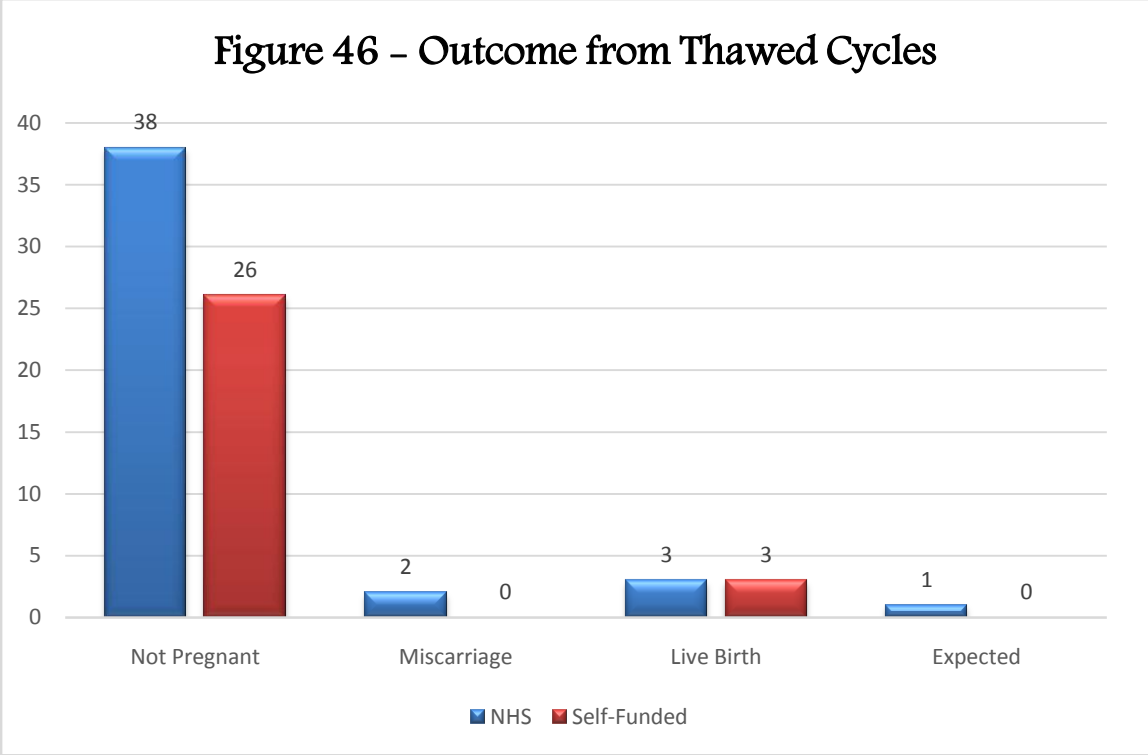


Figure 46 – Outcome from Thawed Cycles
40
35
30
25
20
15
10
5
0
38
26
2
0
3
3
1
0
Not Pregnant
Miscarriage
Live Birth
Expected
NHS
Self-Funded

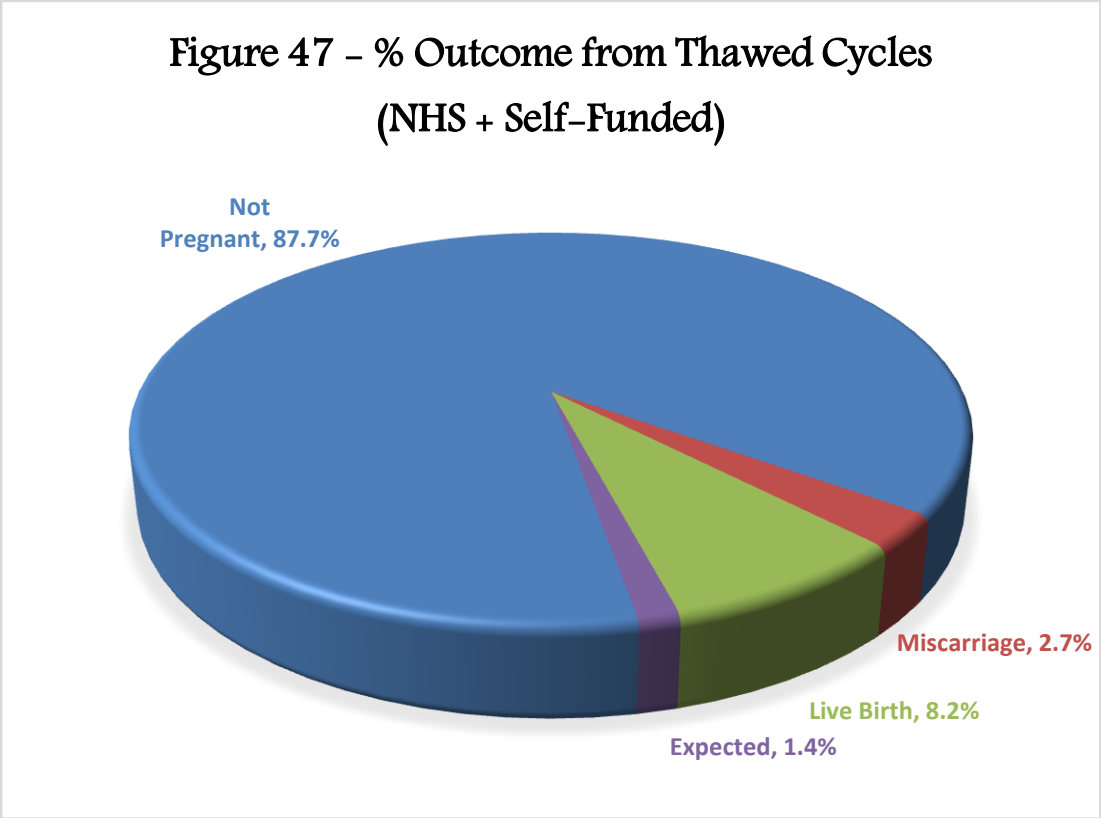
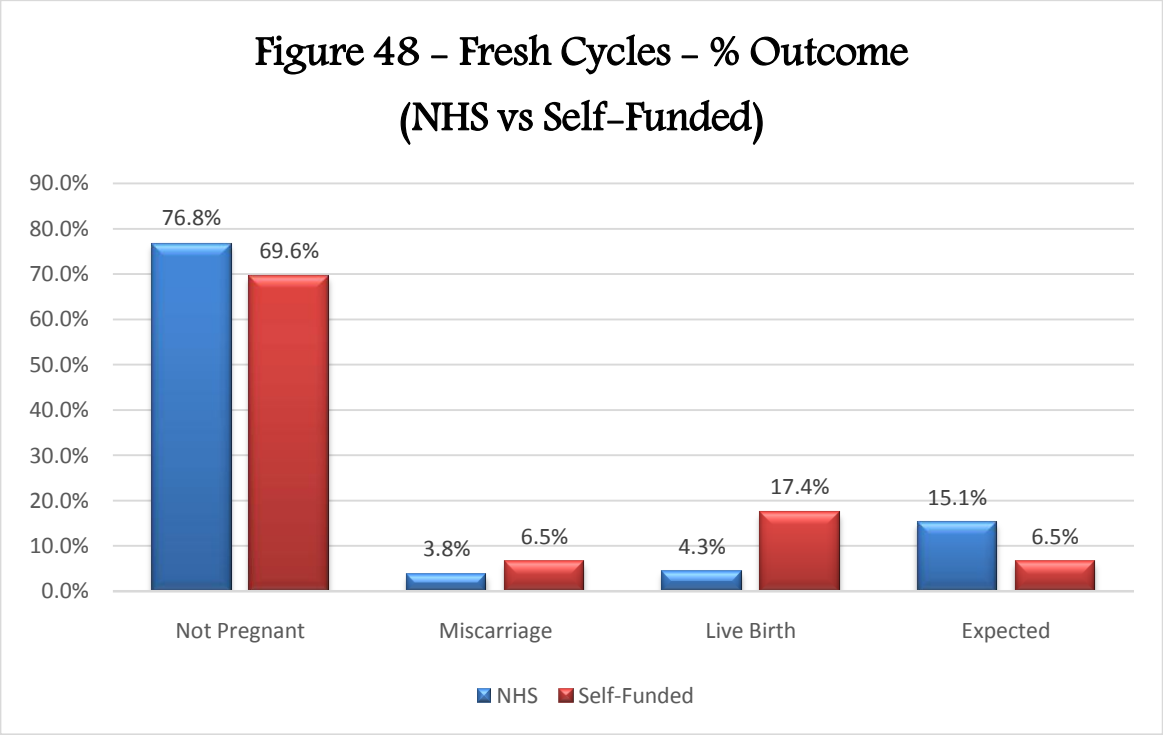


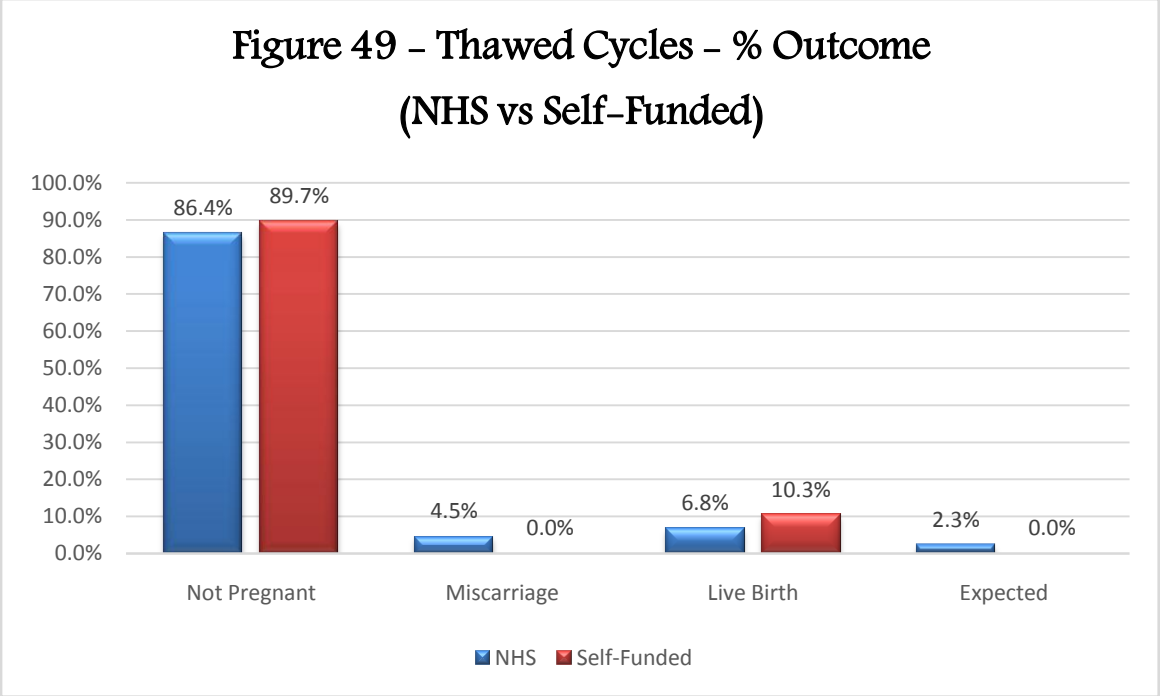
Figure 47 – % Outcome from Thawed Cycles
(NHS + Self-Funded)
Not Pregnant, 87.7%
Miscarriage, 2.7%
Live Birth, 8.2%
Expected, 1.4%

8.3. Cycle Outcomes – NHS vs Self-Funded

The pregnancy rate reported by the private clinics for thawed cycles was 3.4% lower than that reported by the ART Clinic at MDH. In Contrast the pregnancy rate reported by the private clinics for fresh cycles was 7.2% higher than that reported by the ART Clinic at MDH.

The sum of live and expected births from Fresh cycles carried out at MDH was 19.4%, while that for private clinics was 23.9% (Figure 48), this was also due to the fact that MDH reported 7 miscarriages whilst the private clinics reported only 3 miscarriages. Same also applies to the sum of live and expected births from Thawed cycles carried out at MDH which was reported as 9.1% while that for the private clinics was 10.3%, only 2 miscarriages were reported by MDH, while the private clinics reported no miscarriages from thawed cycles (Figure 49).





8.4. Pregnancies by Age

Pregnancies were reported across all age groups. The highest number of pregnancies reported was for women in the 33-36 year old bracket, this contrasts with figures reported in 2016, wherein the highest number of pregnancies reported last year, were registered in the 29-32 age bracket (Figure 50). This was also reflected in the pregnancy rate as percentage of cycles per age group which was highest for women aged 33-36, at 25.4% (Figure 51).

This contrasts well with the pregnancy rate as percentage cycles per age group reported in 2016 wherein the highest group was in couples where the female was less than 28 years of age. It would appear that in 2017, maternal age was not the most important predictive factor for an IVF/ICSI procedure to result in a pregnancy.

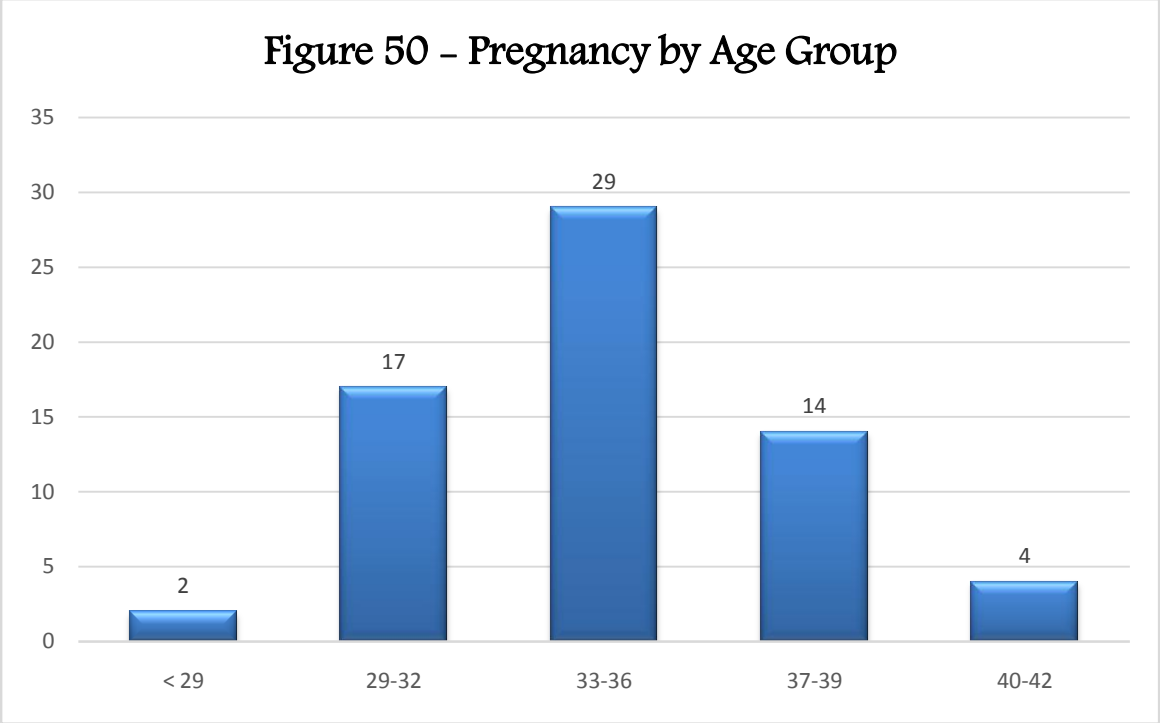


Figure 50 – Pregnancy by Age Group
35
30
25
20
15
10
5
0
2
17
29
14
4
< 29
29-32
33-36
37-39
40-42

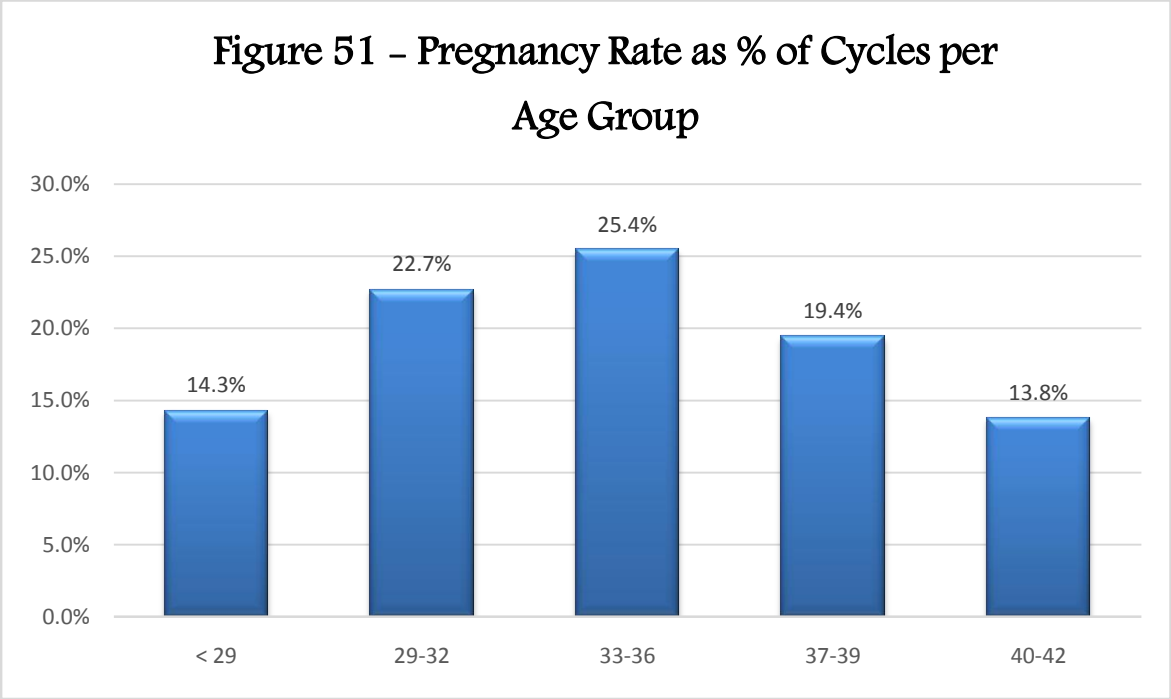


Figure 51 – Pregnancy Rate as % of Cycles per Age Group
30.0%
25.0%
20.0%
15.0%
10.0%
5.0%
0.0%
14.3%
22.7%
25.4%
19.4%
13.8%
< 29
29-32
33-36
37-39
40-42

8.5. Pregnancy Rate per Embryos Transferred

From a total of 270 couples who had an embryo transfer effected, there were 66 resulting pregnancies, or 24.44%, a drop of 1.26% when compared to the previous year.

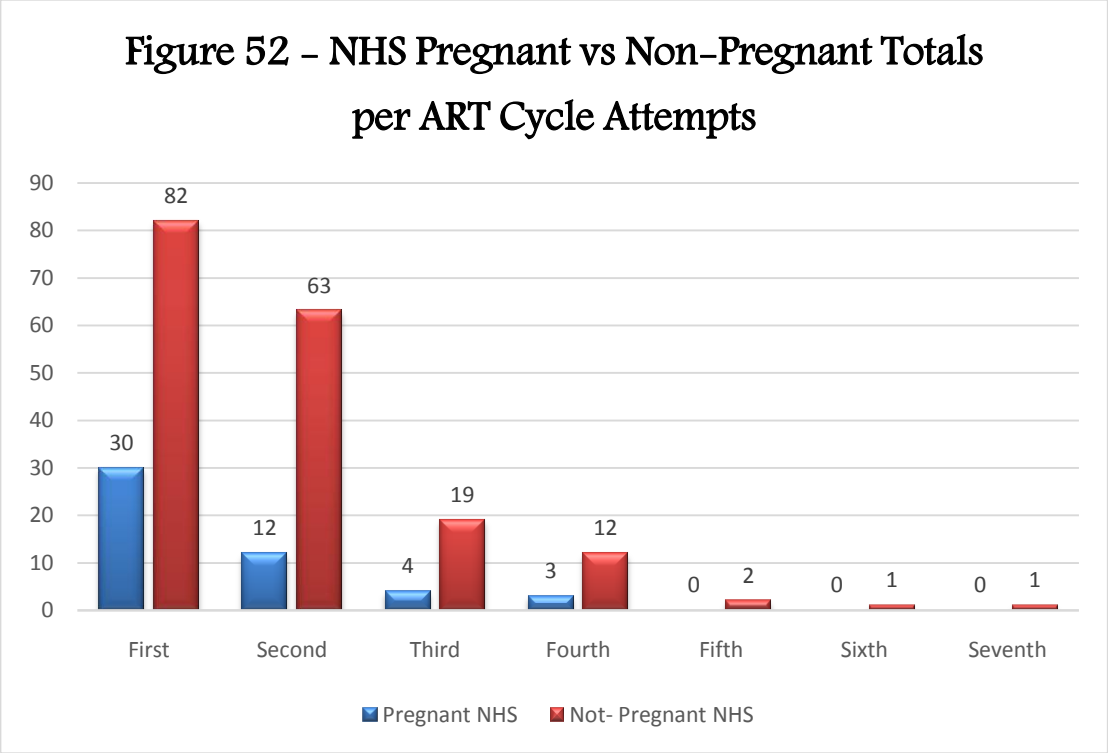
The couples who were most successful at achieving a pregnancy were those who had 2 embryos transferred (33.53%), same as with 2016, however the current calendar year registered an increase of 4.86% over the 28.67% that was reported last year with 2 embryos transferred. These were followed by those couples who had 3 embryos transferred (13.79%). The remaining 6.25% achieved a pregnancy through a single embryo transfer (Table 14). Noteworthy to note is that there was a significant drop in both the pregnancies achieved by 3 embryo transferred and one embryo transferred, drop of 10.74% and 11.14% respectively.

Table 14. Pregnancy Rate per Embryos Transferred

Transferred Embryos	Total IVF/ICSI Procedures	Total Pregnancies	% Pregnancies
0	24	0	0.00%
1	48	3	6.25%
2	164	55	33.53%
3	58	8	13.79%
Total	294	66	22.45%
Total procedures with Embryo transfer	270	66	24.44%

8.6. Pregnancy Distribution per ART Cycle Attempts

Forty one (41) couples (or 27.20%) out of the 66 who got pregnant from cycles carried out in 2017, achieved a pregnancy on their 1st IVF/ICSI attempt, these were achieved by 30 couples who had undergone their cycle at the ART Clinic at MDH and 11 couples who self-funded their treatment. 15 couples (or 15.6%) achieved a pregnancy on their 2nd attempt, 12 from MDH cycles and 3 from the private clinics cycles. 7 couples (23.3%) on their 3rd attempt, these pregnancies were achieved 4 from cycles on the NHS and 3 that were self-funded. The remaining 3 couples (or 15%) all who had undergone their treatment at MDH achieved a pregnancy on their 4th attempt (Figures 52, 53 and 54). No pregnancies were reported for the couples who had undergone their 5th, 6th and 7th attempt.



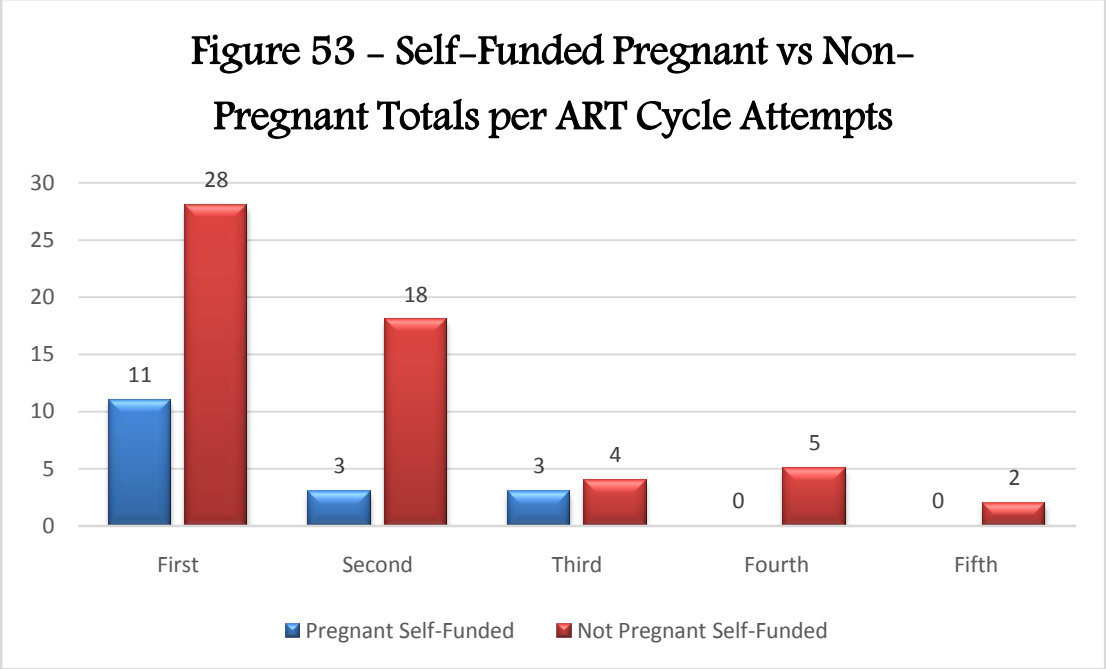


Figure 53 – Self-Funded Pregnant vs Non-Pregnant Totals per ART Cycle Attempts
30
25
20
15
10
5
0
11
28
3
18
3
4
0
5
0
2
First
Second
Third
Fourth
Fifth
Pregnant Self-Funded
Not Pregnant Self-Funded

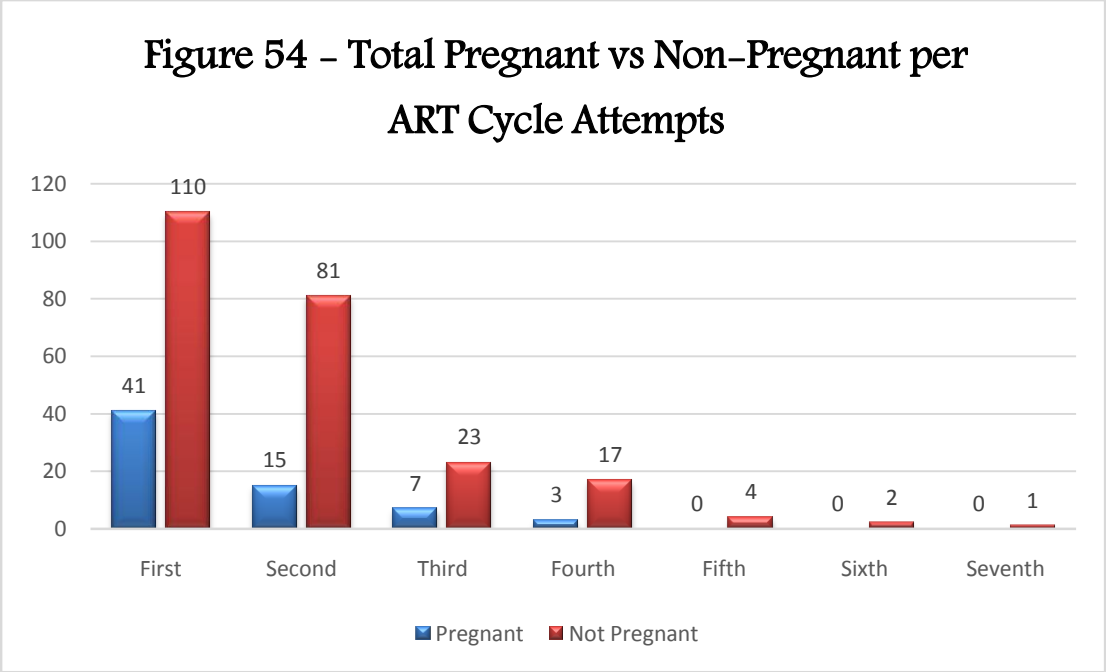
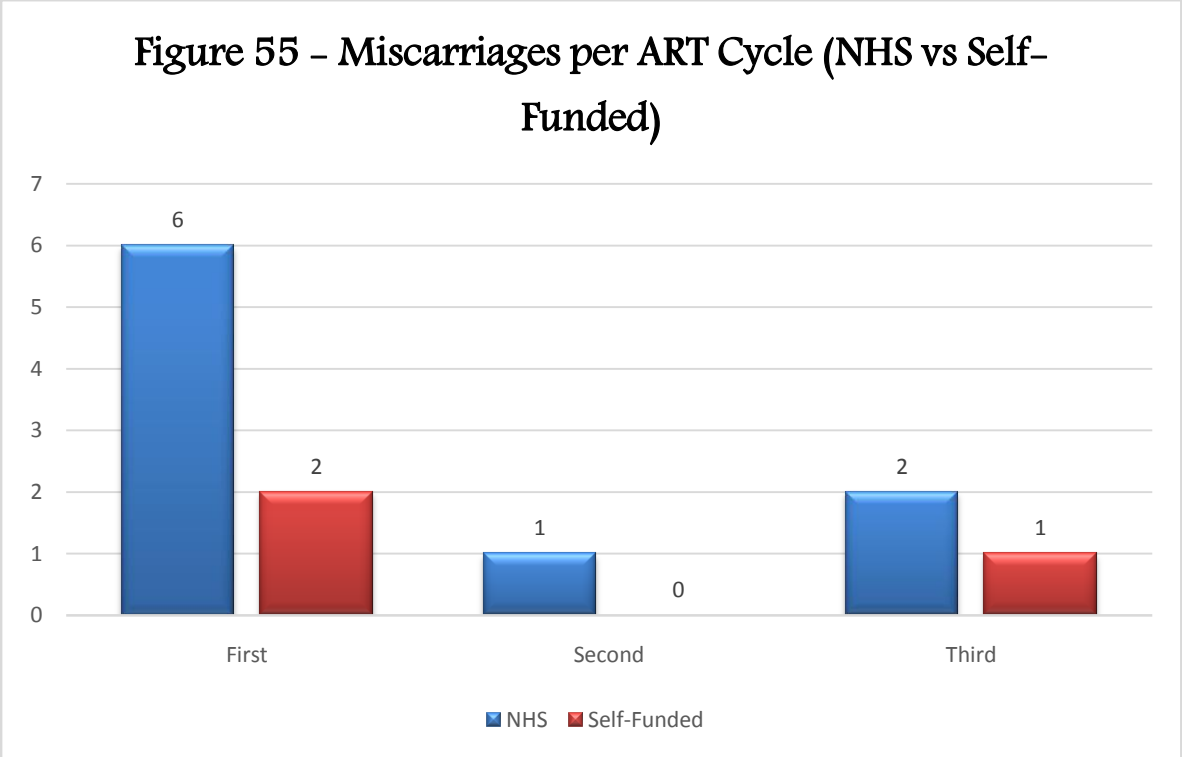
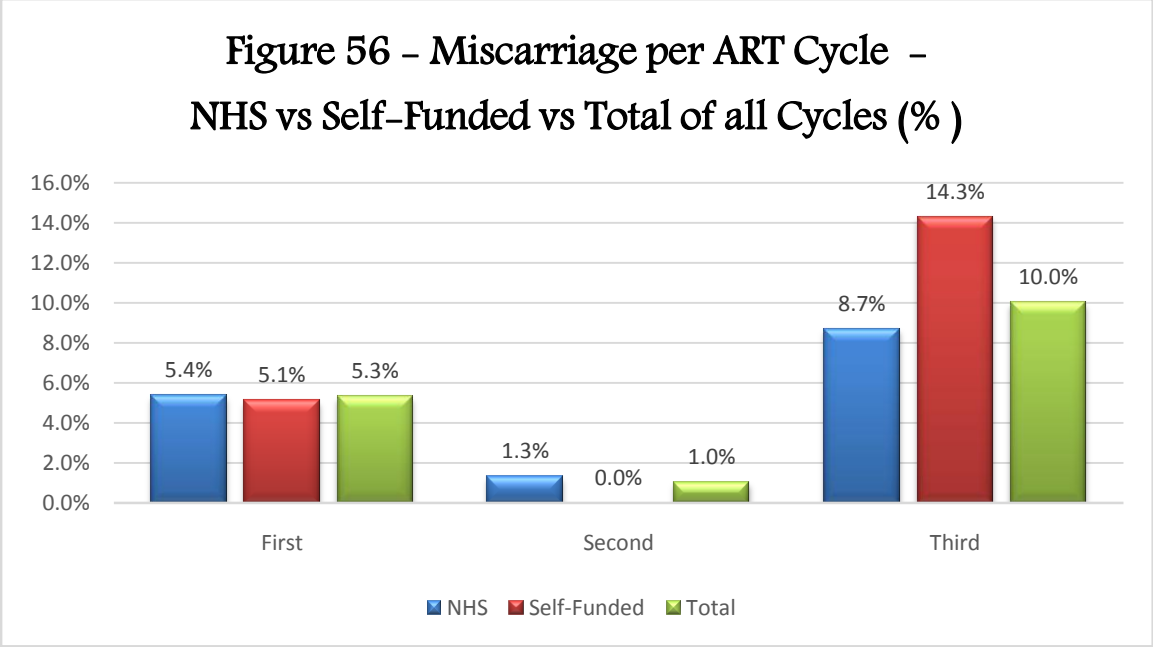


Figure 54 – Total Pregnant vs Non-Pregnant per ART Cycle Attempts
120
100
80
60
40
20
0
41
110
15
81
7
23
3
17
0
4
0
2
0
1
First
Second
Third
Fourth
Fifth
Sixth
Seventh
Pregnant
Not Pregnant

8.7. Miscarriages per ART Cycle

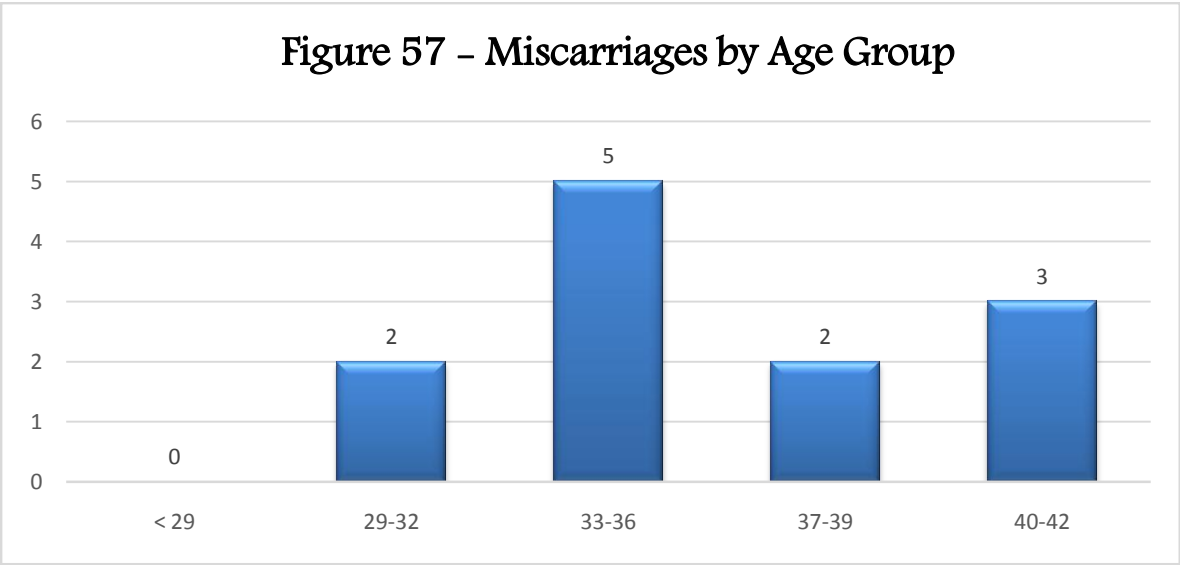
In 2017, a total of 12 miscarriages were reported, 9 from cycles carried out at MDH and 3 from cycles that were self-funded. Eight (8) of the couples who got pregnant on their first IVF/ICSI attempt miscarried. There was one (1) couple who miscarried after a successful 2nd IVF/ICSI attempt. Three (3) couples miscarried after getting pregnant from a 3rd attempt, there were no miscarriages reported from the pregnancies achieved after a successful 4th attempt (Figures 55 and 56).

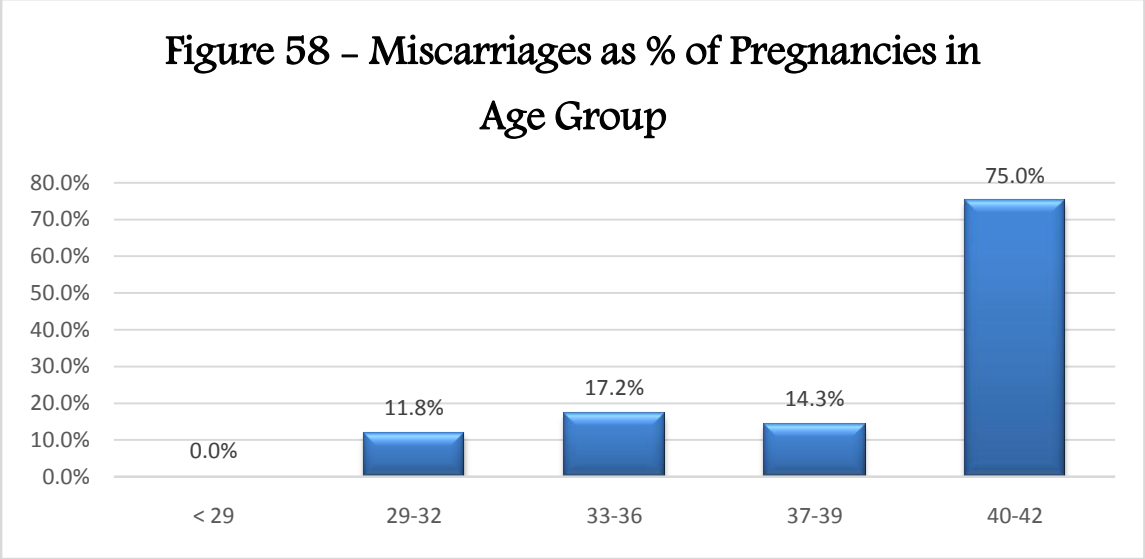




8.8. Miscarriages by Age

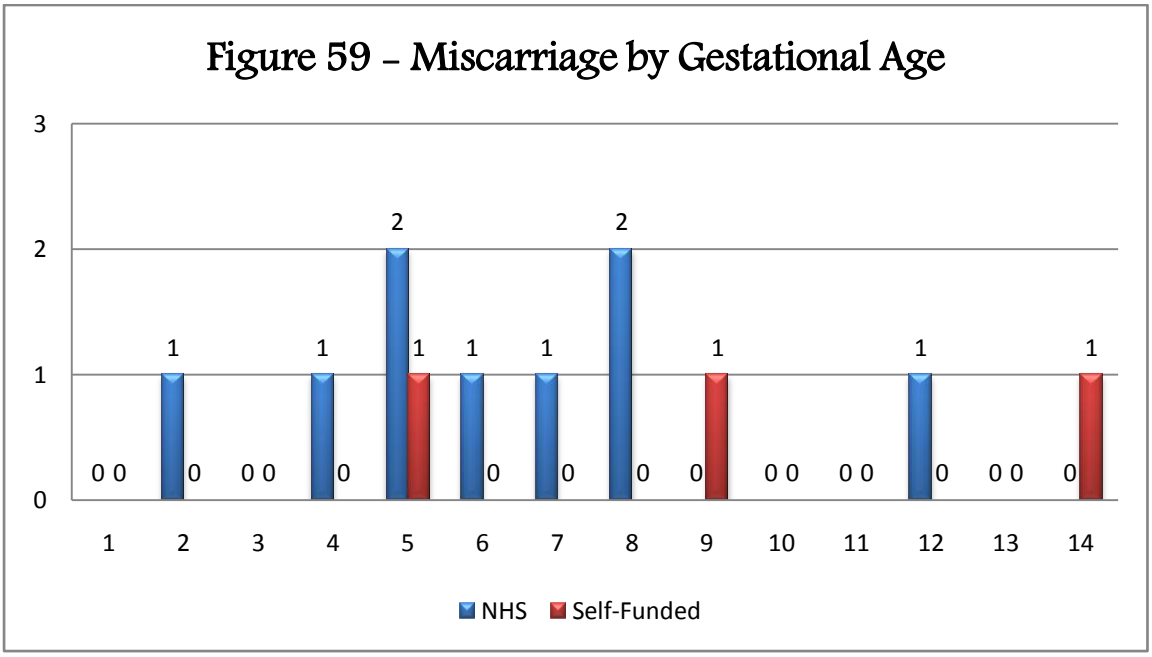
Miscarriages were only reported for women aged 29 and over. There were 2 reported miscarriages for women aged 29-32, 5 miscarriages for women in the 33-36 year old bracket, and two miscarriages were reported for women aged 37-39. Three (3) of the four (4) women aged 40-42 who got pregnant, miscarried resulting in a 75% miscarriage rate for this age group (Figures 57 and 58).





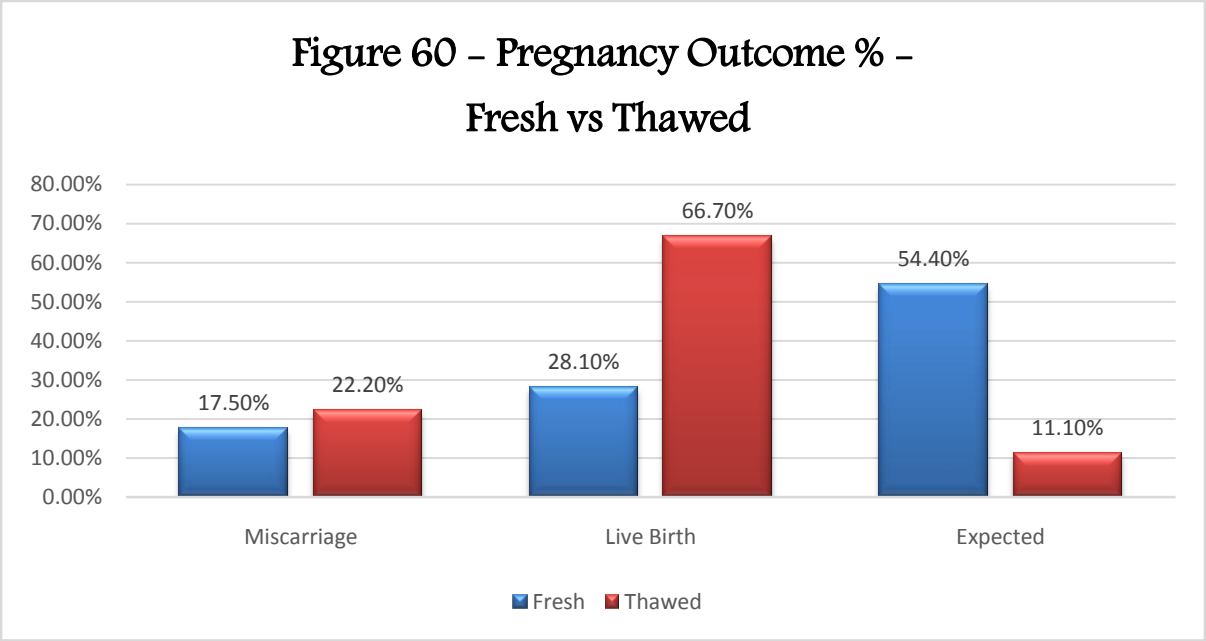
8.9. Miscarriages by Gestational Age

The 12 miscarriages reported were from one woman who was in her 2nd week gestation. One (1) woman miscarried at 4 weeks; another 3 miscarried at 5 weeks; two women miscarried in their 6th and 7th week respectively; two miscarried at 8th week while another 2 women miscarried at the 9th and 12th week respectively. The remaining woman a 30 year old, miscarried a twin pregnancy at 14 weeks gestation (Figure 59).



8.10. Miscarriages from Fresh vs Thawed Cycles

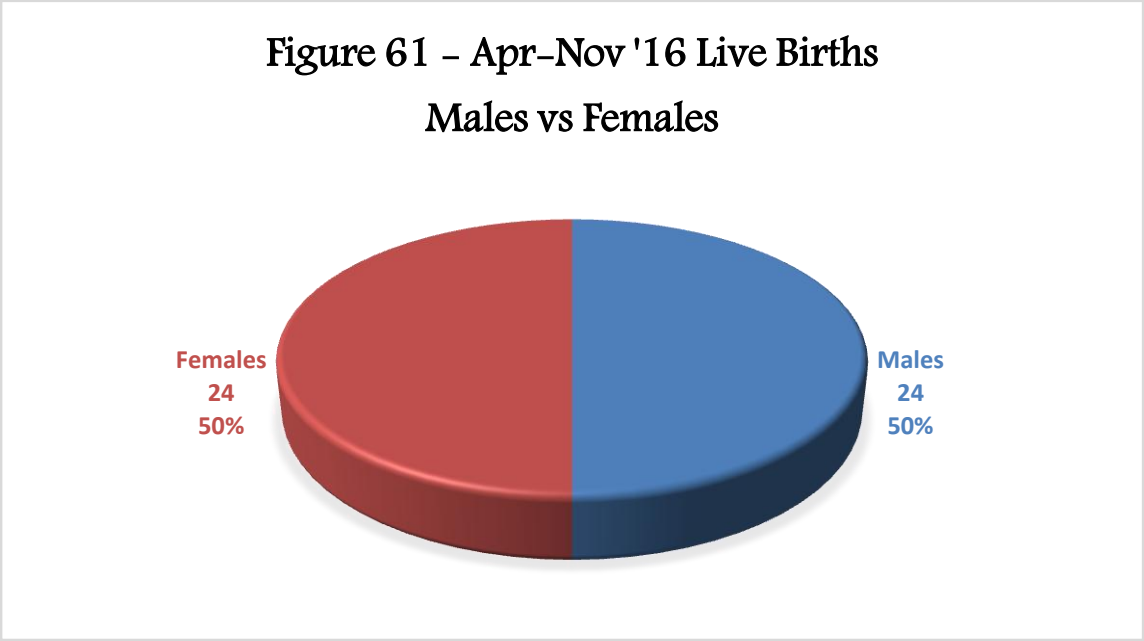
Ten (10) couples, or 17.50%, miscarried after achieving a pregnancy from a Fresh cycle and 2 couples (22.20%), miscarried after a successful Thawed cycle (Figure 60, Table 13).

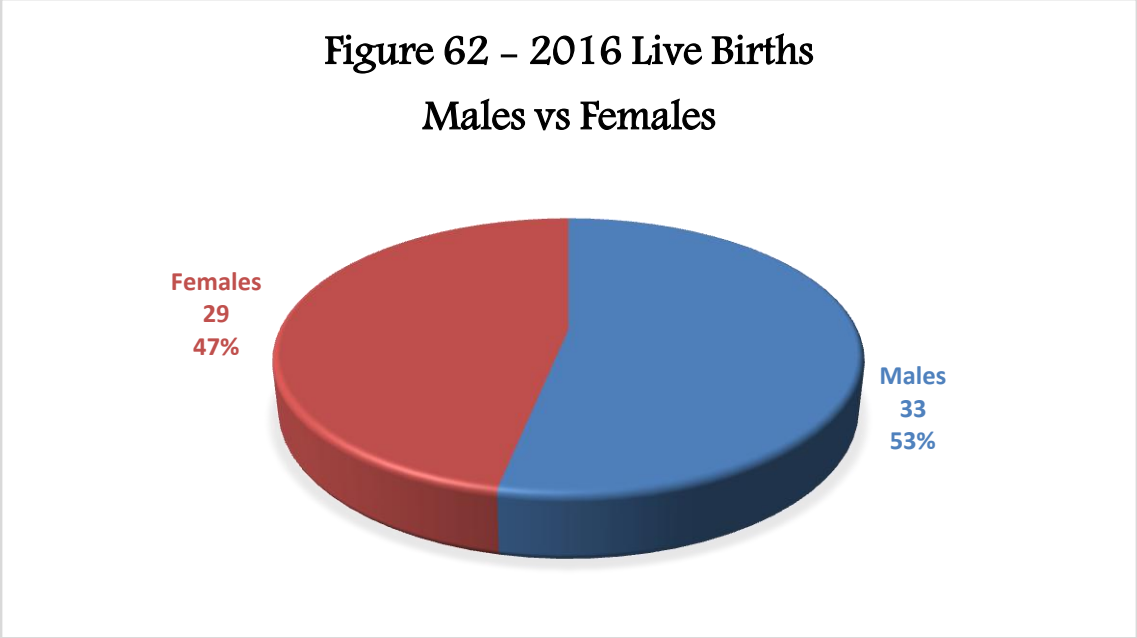


9. BIRTH EVENTS

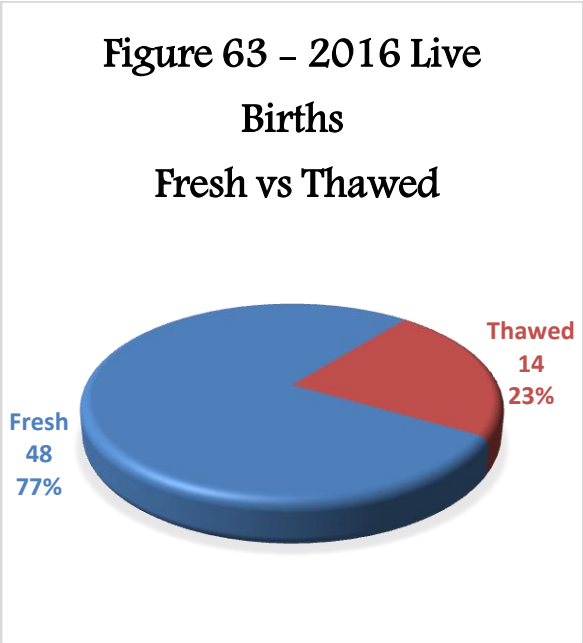
9.1. Births from April – November 2016 Cycles

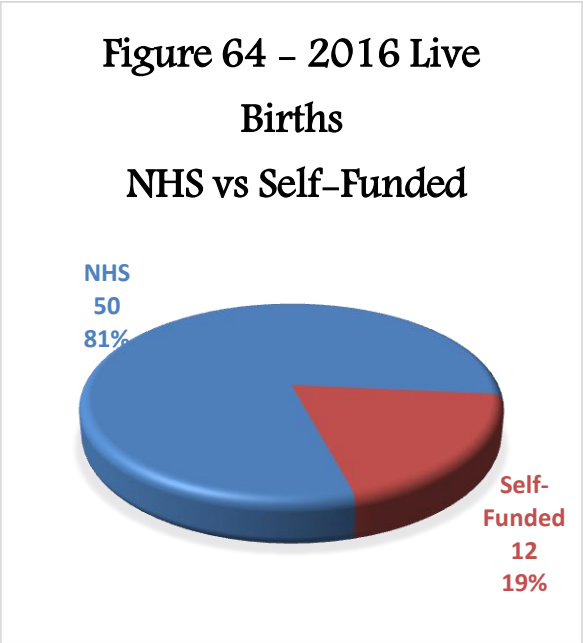
In 2017, Forty eight (48) babies, 24 females and 24 males, were born as a result of cycles performed between April and November 2016 (Figure 61). Hence, a total of 62 babies, 29 females and 33 males, were born out of the 273 procedures carried out throughout 2016 (Figure 62). Anomaly was observed in one of these babies, another baby passed away two days post-birth, (neonatal death), no anomaly was observed in this infant at time of birth.



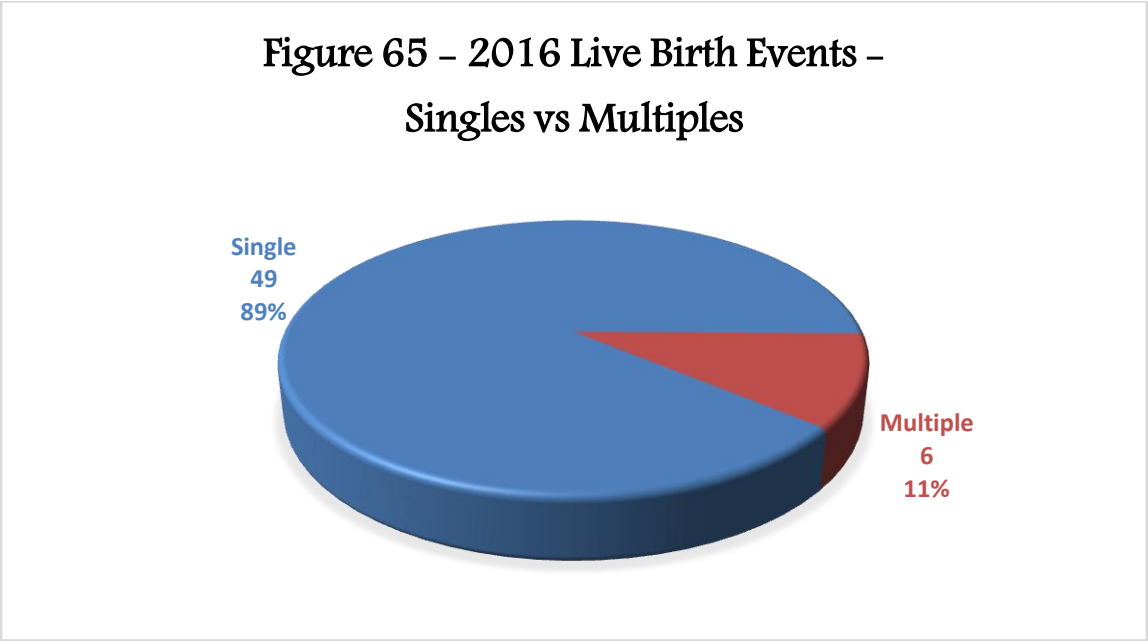


Forty eight (48) babies, or 77.42%, were born out of Fresh cycles and 14 babies were born out of Thawed cycles (Figure 63). Fifty babies or (80.65%) of the babies born out of procedures carried out in 2016 were from procedures carried out at MDH, while the remaining 19.35% were from procedures carried out at the private clinics (Figure 64).





Out of a total of 55 Live Birth Events, there were 49 single births and 6 multiple births. The multiple births consisted of one set of triplets and five sets of twins (Figure 65). During 2016 there was a drop of 11% in multiple births when compared to 2015.



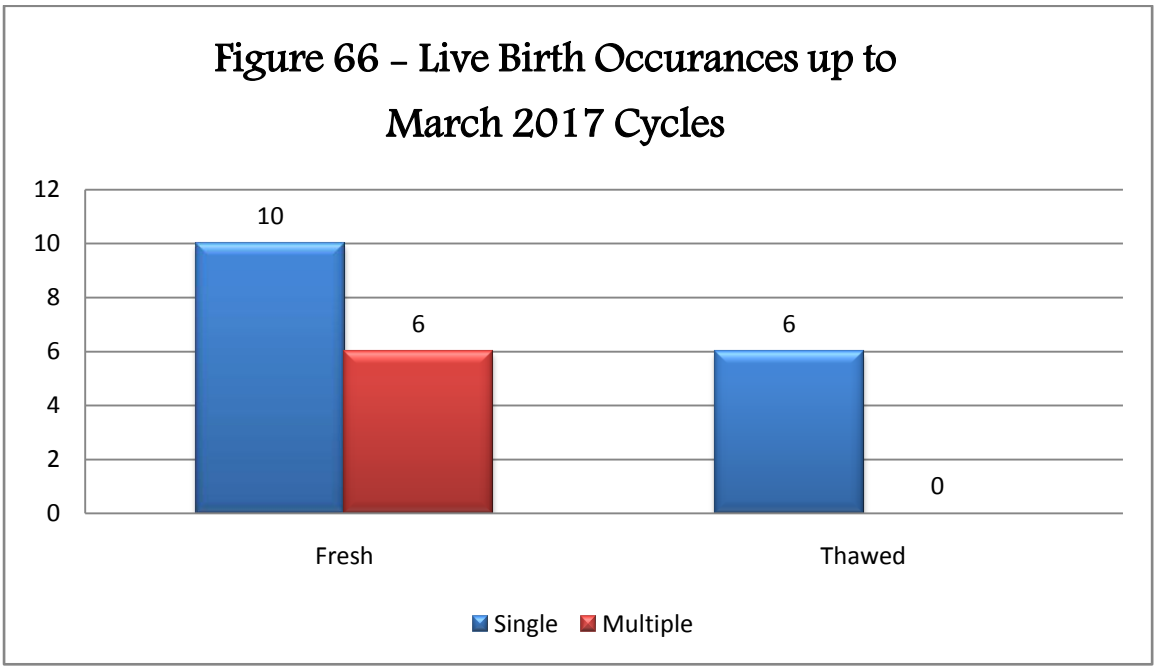
In summary, out of a total of 273 cycles carried out in 2016, 209 couples did not achieve a pregnancy, 9 miscarried, and 55 had a live birth, for a **final Take-Home Baby Rate of 20.15%** (Table 15), **which is 1.18% better than that reported in 2015.**

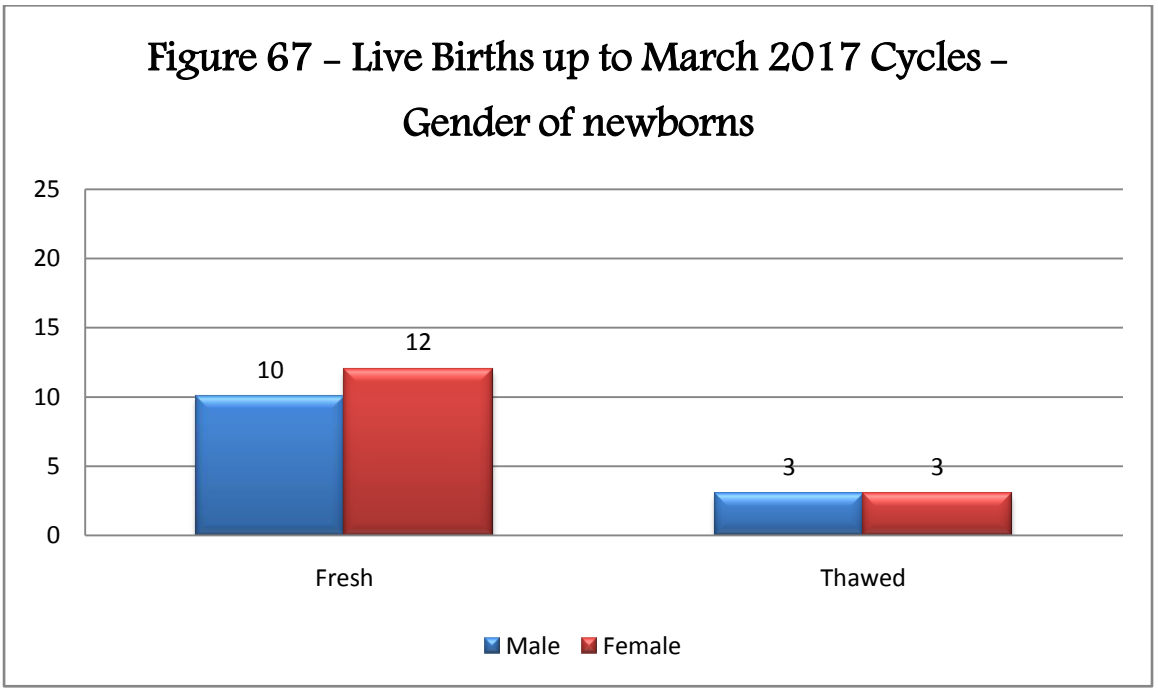
Table 15 – % Take-Home Baby Rate 2016

Cycle Outcome	Qty	% of pregnancies	% of total cycles
Live Birth	55	85.94%	20.15%
Miscarriage	9	14.06%	3.29%
Not Pregnant	209		76.56%
TOTAL CYCLES 2016	273		100.00%

9.2. Birth Events from 2017 Cycles – Fresh vs Thawed

The number of babies born out of procedures carried out between January and March 2017 was 28. Ten (10) singletons and six multiples were born from Fresh cycles. Six singletons were born from Thawed cycles. Babies born were 13 males and 15 females (Figures 66 and 67). No Anomalies were observed in infants born.

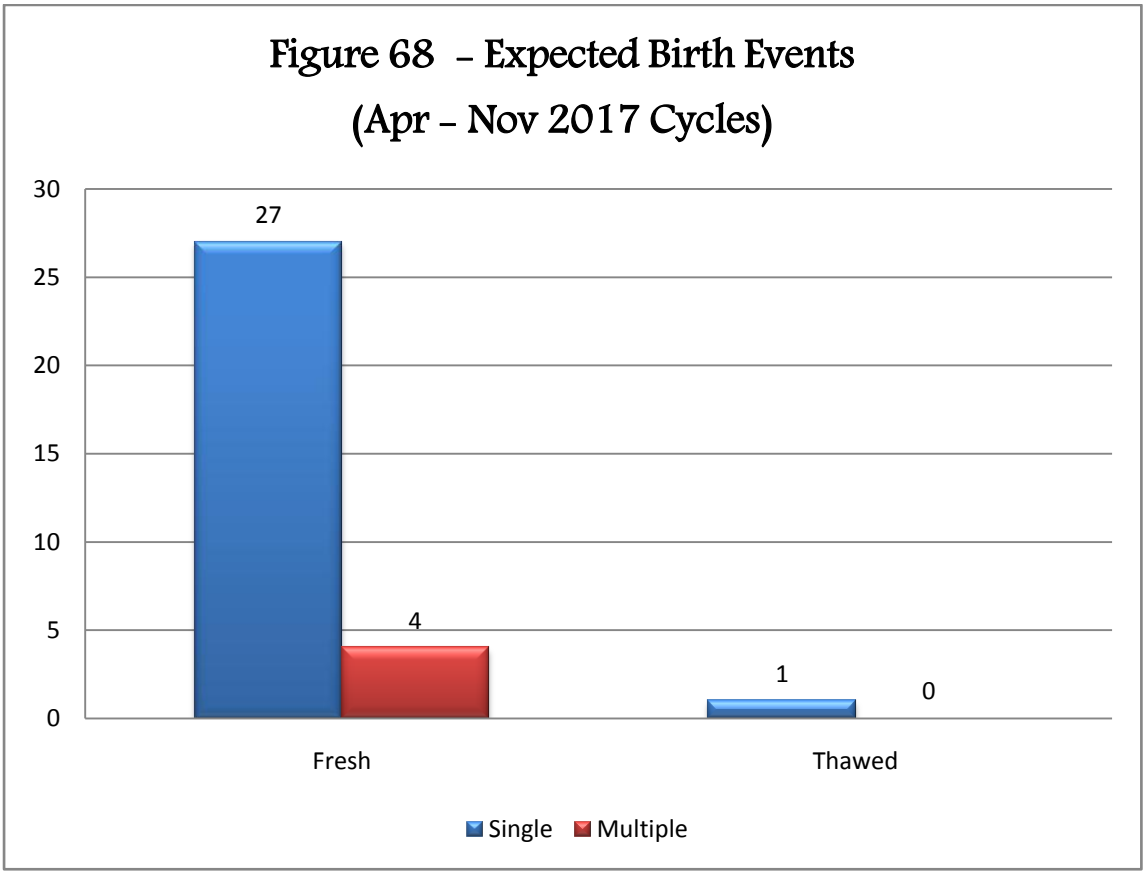




9.2.1. Expected Birth Events from Fresh vs Thawed

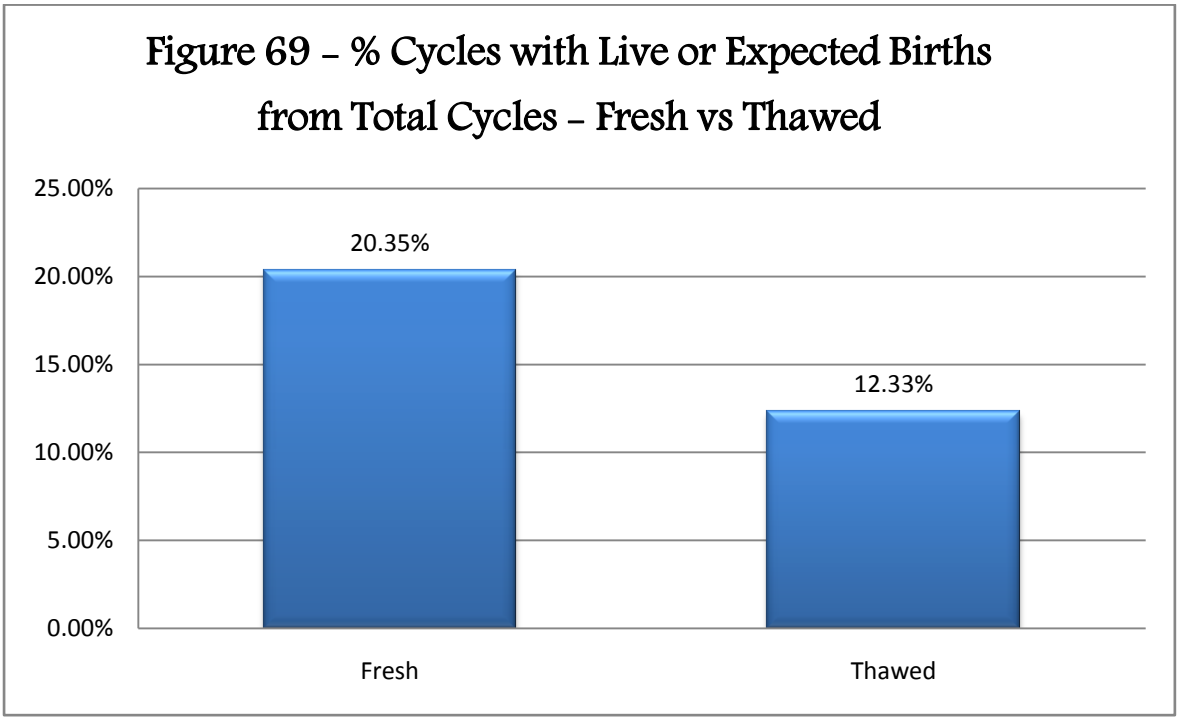
Thirty two (32) birth events are expected from cycles carried out between April and November 2017. Twenty seven (27) singletons and 4 multiples (twins) are expected from Fresh cycles and 1 singleton is expected from Thawed cycles (Figure 68). **The percentage of live and expected births from multiple pregnancies in 2017 is 3.29% of all cycles, an increase of 1.09% over 2016.**

Hence, out of the 54 live and expected births from procedures carried out in 2017, 56 babies are from pregnancies achieved through Fresh cycles, and the remaining 8 babies are from pregnancies achieved through Thawed cycles.



9.3. Maximum Success Rate – Fresh vs Thawed

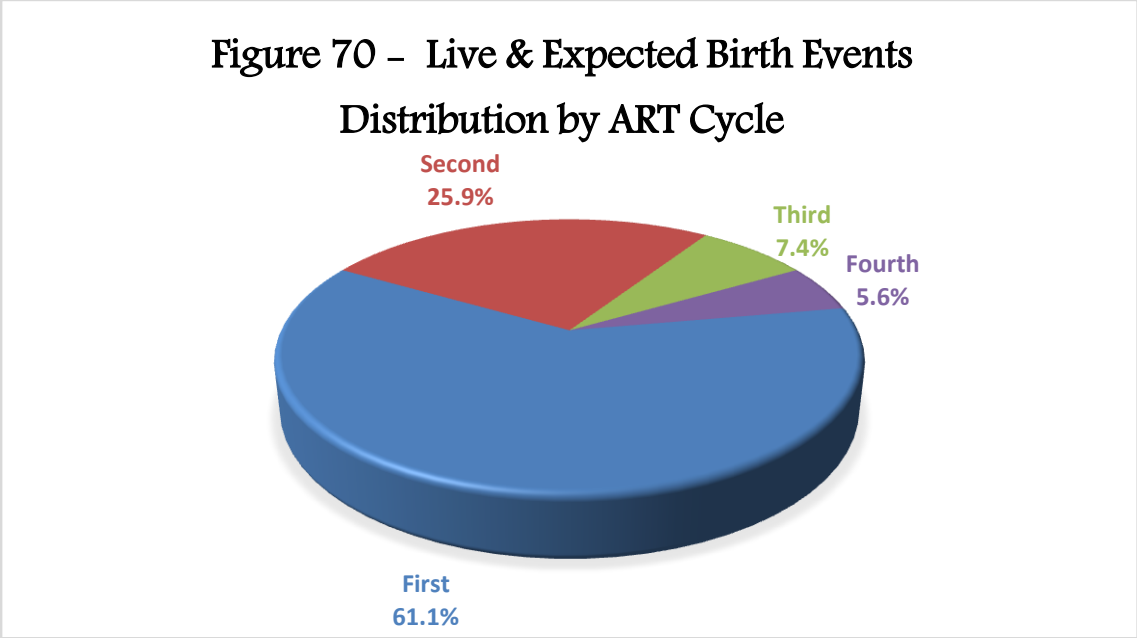
From the **231 Fresh** cycles carried out, there are 47 reported birth events (live + expected), for a maximum success rate of **20.35%,** which is 1.41% lower than last year's 21.76% maximum success rate from fresh cycles. Nine (9) birth events (live + expected) are reported from the 73 **Thawed** cycles performed, for a maximum success rate of **12.33%,** which is 6.6% lower than last year's (Figure 69).



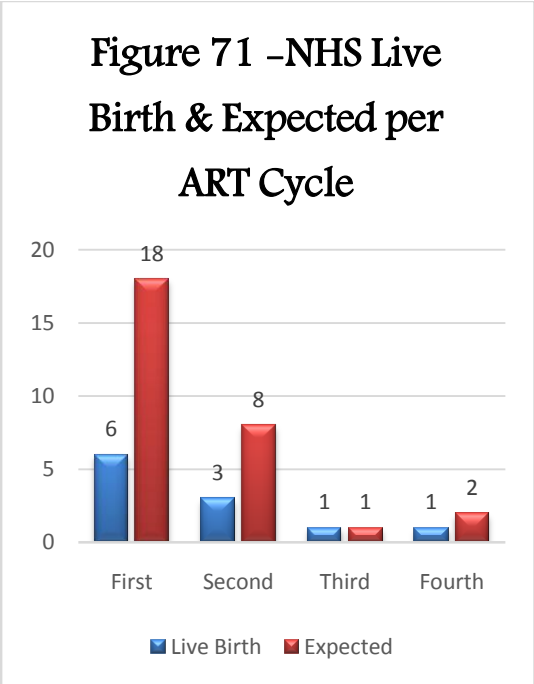
9.4. Birth Events per ART Cycle

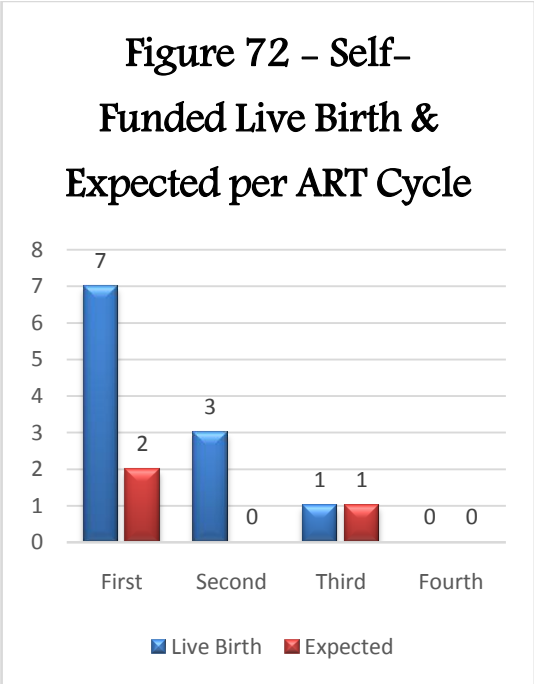
Out of a total of 54 reported birth events (live + expected) from procedures carried out in 2017, there were 33 birth events (61.11%) from couples undergoing their first IVF/ICSI attempt, 14 birth events from a 2nd attempt, 4 birth events from a 3rd attempt, and 3 more birth events from a 4th attempt

(Figure 70). These figures augur well as there is a registered 6.71% increase in birth events from first IVF/ICSI attempt, than those reported in 2016.

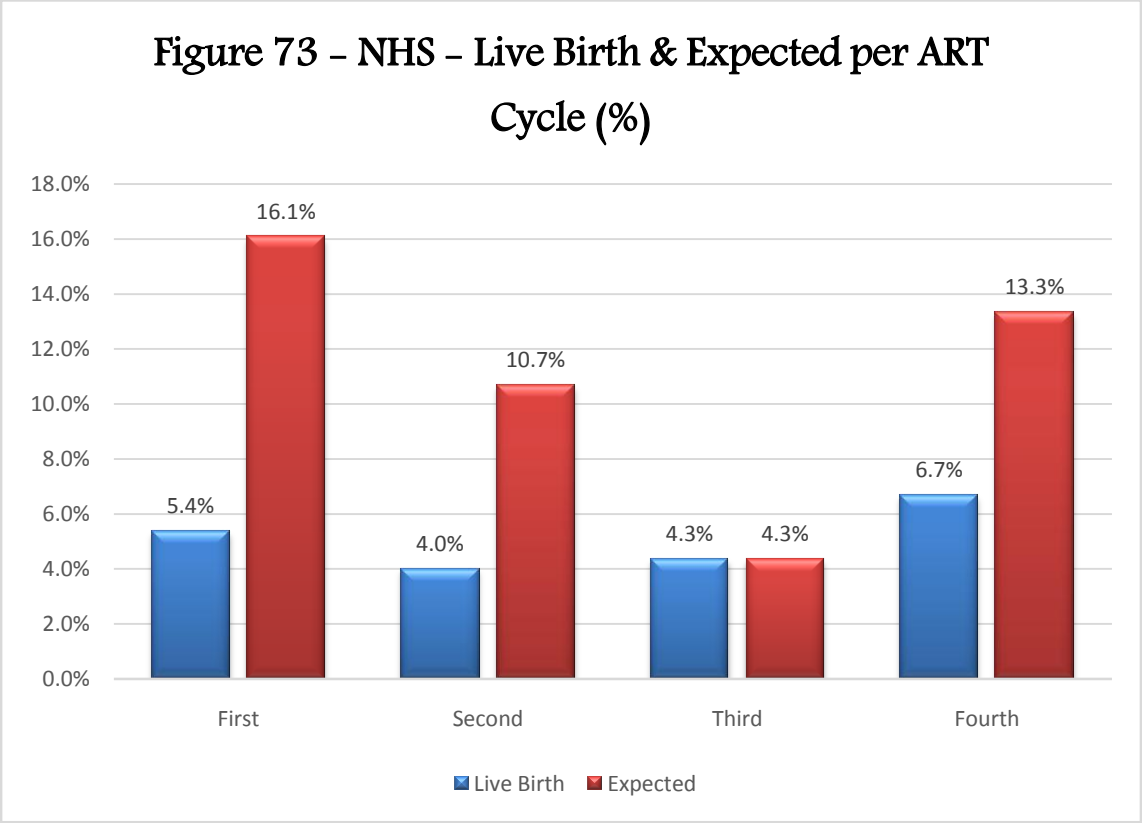


The majority of these birth events (live and expected) 40 couples or 74% of couples experiencing a birth event, are from cycles undergone at MDH, the remaining 14 couples had self-funded their treatment (Figures 71 and 72).





Overall outcome of birth events (live + expected) from all 304 procedures carried out in 2017, show that 21.9% of all couples undergoing their first IVF/ICSI attempt will experience a birth event, 14.6% of the total of couples undergoing a 2nd attempt, 14.6% from a 3rd attempt, and a 15% birth event from couples undergoing a 4th attempt (Figures 73, 74, 75 and 76). As per Figure 74, there were no reported birth events from couples who were undergoing their fourth attempt at the private clinics.



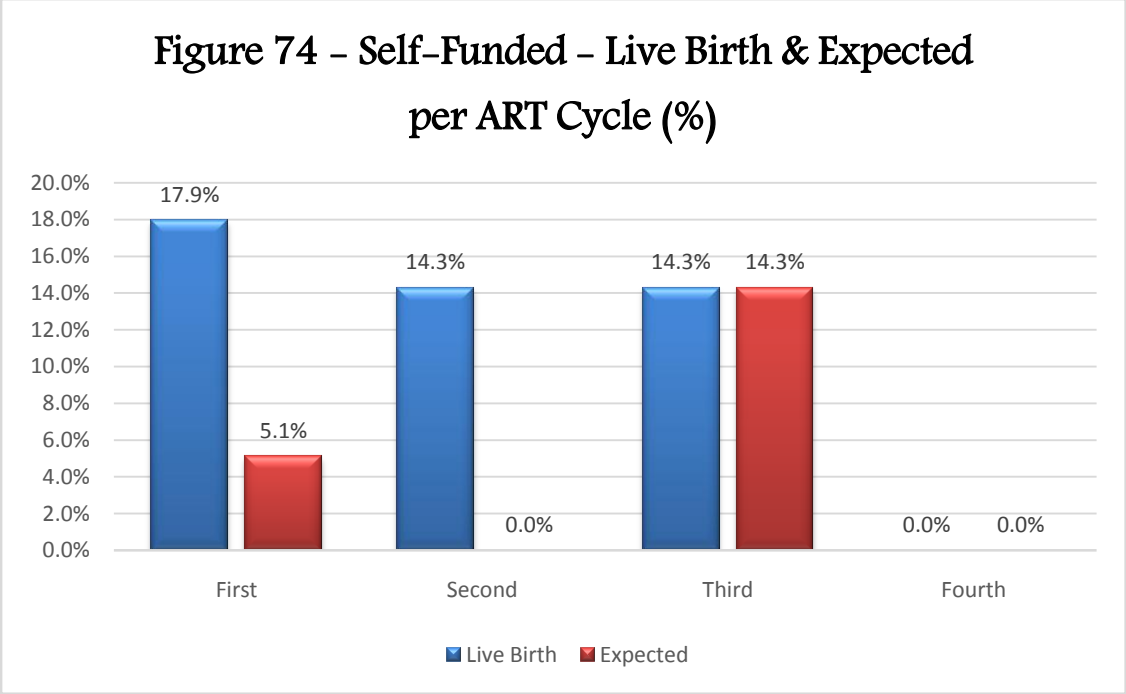


Figure 74 – Self-Funded – Live Birth & Expected per ART Cycle (%)
20.0%
18.0%
16.0%
14.0%
12.0%
10.0%
8.0%
6.0%
4.0%
2.0%
0.0%
17.9%
5.1%
14.3%
0.0%
14.3%
14.3%
0.0%
0.0%
First
Second
Third
Fourth
Live Birth
Expected

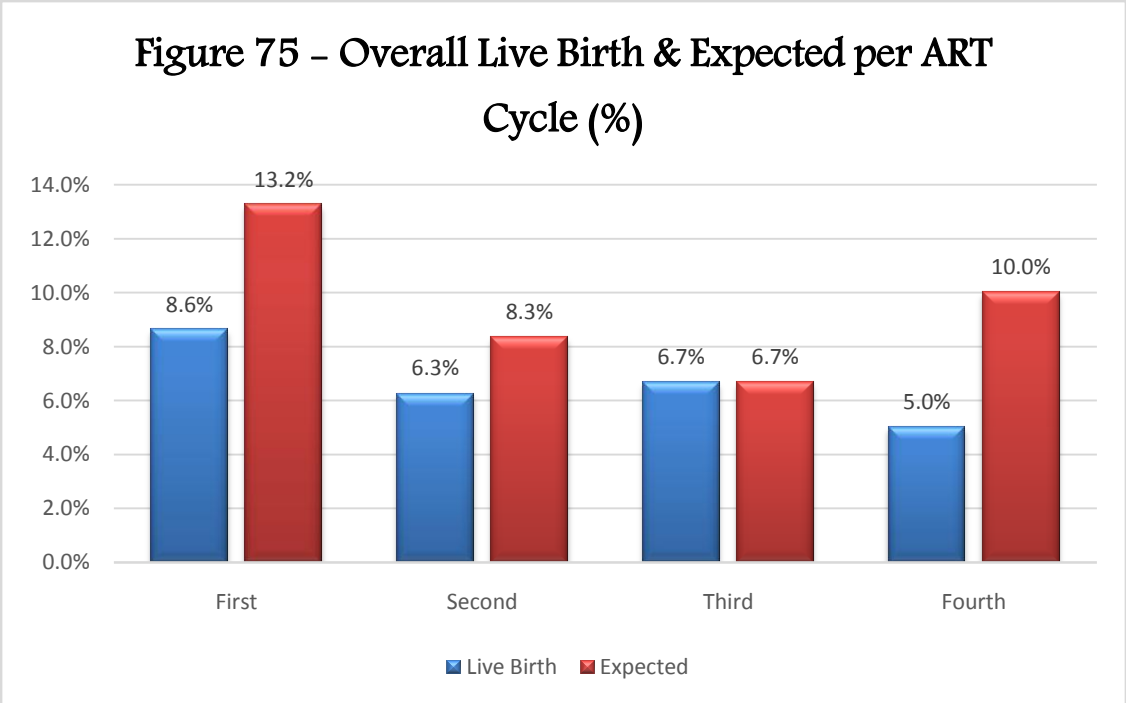
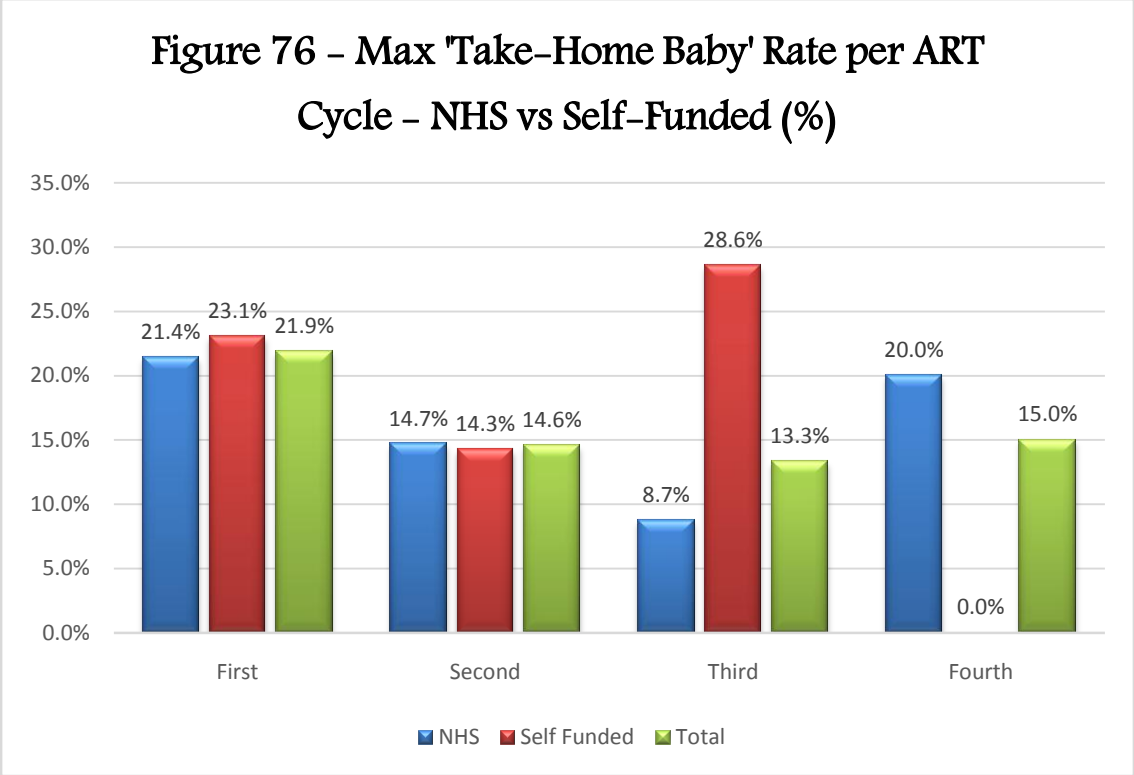


Figure 75 – Overall Live Birth & Expected per ART Cycle (%)
14.0%
12.0%
10.0%
8.0%
6.0%
4.0%
2.0%
0.0%
8.6%
13.2%
6.3%
8.3%
6.7%
6.7%
5.0%
10.0%
First
Second
Third
Fourth
Live Birth
Expected



9.5. Outcome for Approved AFR

As outlined in Section 7.6 above, there were 15 couples who had their Additional Fertilization Request (AFR) approved but did not manage to undergo the IVF/ICSI procedure.

Notwithstanding the fact that the remaining 111 couples had an extra oocyte available for fertilization, the rate of Birth Events (Live + Expected) with multiples (2.70%) is lower than the overall rate of Birth Events (Live+ Expected) with multiples which stands at 3.29%. The total Birth Events (Live + Expected) for couples with an approved AFR who had undergone an IVF/ICSI procedure stand at 14.41% (Table 16).

Table 16. Outcome for Approved AFRs

No of Approved AFR	No of Procedures undergone from Approved AFR	No of Pregnancies	Miscarriages	Expected & Live Birth Events	Singles	Multiples
126	111	22	6	16	13	3
% of Procedures undergone from Approved AFR		19.82%	5.41%	14.41%	11.71%	2.70%

These results show that for this population, approval for the fertilization of 3 oocytes instead of 2 was of benefit since, even though an extra oocyte was available for fertilization, these couples still fell short of reaching the overall Maximum Success Rate, which is the sum of the live and expected birth events, as illustrated in Table 16.

9.6. Percentage Maximum Success Rate – 'Take Home Baby' Rate

In conclusion, from the 66 couples who achieved a pregnancy in 2017, 22 (33.34%) had a live birth, 32 (48.48%) are still expecting, and 12 couples (18.18%) miscarried.

Out of a total of 304 cycles carried out, **7.24%** of couples had a live birth, **10.53%** are still expecting, while **3.95%** miscarried.

Consequently, the maximum percentage success rate, or 'Take Home Baby' rate for calendar year 2017 is 17.77%, resulting in a 2.38% drop from 2016. (Table 17).

Table 17. % Maximum Success Rate – 'Take Home Baby' Rate 2017

Pregnancy Outcome	Qty	% of pregnancies	% of total cycles	% Max Success – 'Take Home Baby' Rate
Live Birth	22	33.34%	7.24%	
Expected	32	46.48%	10.53%	17.77%
Miscarriage	12	18.18%	3.95%	

10. Conclusion

The number of IVF/ICSI procedures carried out in Malta in calendar year 2017, has increased by 11.35% when compared to 2016. This was due to an increase in Government-funded cycles.

ICSI was the preferred procedure of choice in 91.12% of all procedures carried out by the licensed clinics. There were 66 (21.71%) reported pregnancies out of all cycles started – a drop of 1.73% from 2016. As with last year, Thawed cycles were less effective than Fresh treatments, with a larger percentage of Embryo transfers, pregnancies, and birth events (live + expected) reported from Fresh cycles *vis-a-vis* Thawed cycles. *The* ***maximum percentage success rate****, or* ***'Take Home Baby' rate*** *which implies a birth event and is the most meaningful measure of treatment success*, stands at **17.77%**, which is 2.38% lower than last year.

The Embryo Protection Authority shall keep providing guidance and support to all the licensed ART clinics in Malta so as to ensure that they are operating under the highest standards. Moreover, as the Regulator, the Authority will keep on striving to ensure that local ART Clinics comply with the obligations and requirements imposed by or under the Embryo Protection Act 2012.

Judge Philip Sciberras UOM

Chairperson

Ms. Simone Attard

Executive Director