The Bridge Clinic

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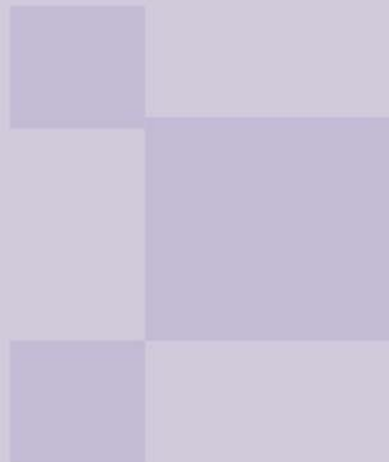
Our Mission

We strive to achieve pregnancy
for couples who desire children
using our knowledge of the
Science of Reproduction.



The Bridge Clinic

BOARD OF DIRECTORS

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Mr. A. Dabiri
Dr. (Mrs.) P. I. Jackson Ajayi
Dr. R. A. Ajayi (Managing Director)

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Adepeju Adegoke (HR/Admin)
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Mudasiru Ojo (Accounts)
Jane Ajaegbo (Quality officer)
Gloria Mamwa-Ndeti (PA to the MD)

LAGOS CLINICAL STAFF

Consultant Gynaecologists

Dr. R. A. Ajayi
Dr. A. I. Arilesere
Dr. A. A. Ogunmokun

Embryologists

Femi Akinrinola
Dayo Yusuf
Shola Adewale
Omonigho Osemeikhian

Client Co-ordinators

Rita Inyang
Stella Agu
Simisola Akintujoye
Sandra Ahmed
Promise Ubali
Ebele Onwuagbaizu
Pamela Ekwurumadu
Bunmi Oderinu

PORT HARCOURT CLINICAL STAFF

Consultant Gynaecologists

Dr. Vad Oriji
Dr. Preye Fiebai (Part time)

Embryologists

Nonso Daniels

Client Co-ordinators

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The Bridge Clinic

Infertility is a major public health issue in Nigeria and it is estimated that approximately 1 out of every 4 couples will experience some difficulty in achieving a pregnancy. The treatment of infertility is difficult and since the introduction of In Vitro Fertilisation (IVF) in 1978, IVF has evolved to become the cornerstone of fertility treatment all over the world and most couples experiencing delay with conception will require IVF (and Intra-cytoplasmic Sperm Injection) (ICSI) to achieve pregnancy.

The Bridge Clinic was set up to provide high quality fertility treatment including IVF (and ICSI) to Nigerians in Nigeria. Our Lagos Clinic began operations in 1999 and our Port Harcourt Clinic in 2003. Since inception, we have completed over 3,000 IVF/ICSI treatment cycles with the birth of 604 babies following treatment at both clinics.

It is a legal requirement in developed countries like the United Kingdom (UK) that all clinics carrying out fertility treatments that involve human gametes such as IVF are licensed by the Human Fertilisation and Embryology Authority (HFEA). Unfortunately there are no such regulatory authorities in Nigeria, but we at the Bridge Clinic recognising the importance of such regulation have always functioned as if we were one of the clinics regulated by the HFEA.

The HFEA advises that IVF clinics set up an ethics committee to supervise their activities and ensure that all these activities fall within the moral and ethical framework of the society. The Bridge clinic set up an ethics committee in 1999 as one of the conditions for the involvement of our technical partners from Kings college Hospital, London. Our ethics committee has set up guidelines within which the activities of the clinic are regulated. For example, all clients requesting surrogacy arrangements must be presented to the ethics to ethics committee on cases by case basis as are all single women requesting the use of donor sperm to name a few. We have found the ethics committee extremely useful over the years. Similarly, the HFEA mandates that independent counseling services be available to all clients attending the clinic to assist with the difficult decisions the couples have to make during fertility treatment. The Bridge clinic has implemented independent free counseling services as one of our service offerings to all our clients since 2000.

The Bridge Clinic

The European Tissue & Cells directive (2006) mandates that all clinics carrying out IVF, implement a quality management program according to ISO 9001:2000 guidelines and most of the clinics in the United Kingdom are now getting certified as inspections starts in April 2007. I am pleased to report that we anticipated this initiative and we received international certification of our quality management system according to ISO 9001:2000 guideline from TUV Austria as early as 2004 ahead of most of the clinics in the United Kingdom.

The widely publicised problems with gamete mix-up in two UK Clinics led the HFEA to mandate that all Clinics carrying out IVF services introduce a witnessing program to control all activities that involves the handling of human gametes to eliminate the risk of gamete mix up. The bridge clinic introduced a witnessing program as an essential part of our treatment program in 2003.

The HFEA performs an annual audit of the results of treatment from all licensed clinics in the United Kingdom and publishes these results in the HFEA annual report which is available on the internet. We have always had informal audits from Dr Virginia Bolton formerly of Kings College Hospital now at St. Thomas Hospital, London, who is also an HFEA inspector, and Mr John Parsons of King's college Hospital, London but we have not published the results of these audits. These published results are an important guide to clients seeking IVF treatment and as part of our objectives of providing quality IVF services in Nigeria, we invited the international audit firm of Akintola Williams Deloitte to carry out a verification exercise of the results of treatment at The Bridge Clinic and we present these results for your kind attention.

Dr. R. A. Ajayi FRCOG
Managing Director

EXECUTIVE SUMMARY

INTRODUCTION

Akintola Williams Deloitte has been requested to review the Standard Operating Procedures and verify the clinical data in respect of Intracytoplasmic Sperm Injection (ICSI), In-Vitro Fertilization (IVF) and Intrauterine Insemination (IUI).

SCOPE AND OBJECTIVES

The objective of this engagement is to assist the Bridge Clinic to independently verify the clinical data maintained with respect to ICSI Cycles, In-Vitro Fertilization (IVF) and Intrauterine Insemination (IUI) and comment on the adequacy of the control procedures in place for the collation of the data.

The work areas covered during the course of the assignment include review of operating procedures, test of controls and substantive verification of clinical data collated from 1999 to July 2005.

The review covered the following departments:

Clinical Department;

Laboratory Department;

Nursing Department; and

Data Security Department.

OUR APPROACH

The procedures and associated findings are as follows:

1. We reviewed the Standard Operating Procedure and the Quality Manual of each operational department (Clinical, Laboratory and Nursing)
2. We interviewed the Process Owners to confirm their understanding of what their responsibilities are as stated in the Standard Operating Procedure and what they actually do.
3. We obtained the results of Intra cytoplasmic Sperm Injection (ICSI) In vitro Fertilisation (IVF) and Intrauterine Insemination (IUI) from the Laboratory Department and carried out the steps required for each of the Assisted Reproductive Technology (ART) as agreed with the department.
4. We selected samples from the list of clients that were pregnant for each year under review.
5. We reviewed the case notes of the clients, (samples) selected.
6. We checked their names to different registers like Semen Analysis Register, ICSI Register, Embryo Transfer Register, (Orange Book), Pregnancy Register and Pregnancy Test Register Cardex Box where applicable.
7. We checked their names on Infertility Database System (IDS) except for those of Port Harcourt
8. We compared our result with the Clinic's result.

We were not engaged to and did not conduct an audit, the objective of which would be an expression of opinion on the figures in the financial statements. Accordingly, we do not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of the Board of Directors and management of The Bridge Clinic and is not intended to be and should not be used by anyone other than these specified parties.

STATEMENT OF RESPONSIBILITIES

This review has been performed in accordance with our terms of reference. Because of inherent limitations in any internal control system, errors or irregularities may occur and not be detected. In addition, the scope of our work would not have necessarily identified all weaknesses in internal controls. Also, projection of the above evaluations to future periods is subject to the risk that the policies and procedures may become inadequate because of changes in conditions, or that the degree of compliance with those policies and procedures may deteriorate.

The matters raised in this report are only those which came to our attention during the course of our review and are not necessarily a comprehensive statement of all the weaknesses that exist or all improvements that might be made. Recommendations for improvements should be assessed by you for their full commercial impact before they are implemented.

Our report has been prepared using information supplied for the review by, and through discussions with the management and other personnel of the Clinic. The scope of our work did not involve subjecting all the information supplied to us to normal audit procedures. Hence, as you will appreciate, we have not performed the audit steps necessary to enable us to express an audit opinion.

This report has been prepared solely for your use as management and should not be quoted in whole or in part without our prior written consent from Akintola Williams Deloitte. No responsibility to any third party is accepted as the report has not been prepared, and is not intended, for any other purpose. Our report should not be disclosed to a third party without our consent. If our consent is given, and our report is disclosed to a third party, we would ask you to draw their attention to these clauses contained in the Statement of Responsibilities.

The accompanying report is intended solely for the benefit of management of The Bridge Clinic, and is not intended to be used for any other purpose.

We would like to take this opportunity to thank The Bridge Clinic's staff for their co-operation during the exercise.

Akintola Williams Deloitte

Akintola Williams Deloitte

TABLE 1: CONSOLIDATED ICSI AND IVF RESULTS (1999 - 2005)

Year	Treatment Cycles (TC)	Embryo Transfers (ET)	Positive (POS)	Early Pregnancy Loss (EPL)	Clinical Pregnancy (CP)	CP Rate Per ET (%)	No. Of Live Births (LB)	Multiple Birth (MB)
1999	97	79	17	3	14	17.7	14	5
2000	256	201	45	8	37	18.4	30	10
2001	426	321	87	23	64	19.9	54	14
2002	423	337	101	34	67	19.9	56	18
2003	459	396	132	37	95	23.9	82	21
2004	492	432	134	25	109	25.2	94	19
2005	529	478	155	34	121	25.3	107	19
OVERALL	2682	2244	671	164	507	22.5	437	106

TABLE 2: RESULTS OF ICSI CYCLES USING OWN EGGS AND EJACULATED SPERMS (1999 - 2005)

Year	Treatment Cycles (TC)	Embryo Transfers (ET)	Positive (POS)	Early Pregnancy Loss (EPL)	Clinical Pregnancy (CP)	CP Rate Per ET (%)	No. Of Live Births (LB)	Multiple Birth (MB)
1999	68	57	12	1	11	19.2	11	4
2000	235	184	42	7	35	19.0	28	10
2001	406	307	84	21	63	20.5	53	13
2002	379	297	87	29	58	19.5	48	15
2003	393	332	106	26	80	24.1	69	19
2004	422	365	115	21	94	25.7	81	17
2005	427	384	122	30	92	23.9	82	10
OVERALL	2330	1926	568	135	433	22.5	372	88

TABLE 3: AGE ANALYSIS OF THE RESULTS OF ICSI CYCLES USING OWN EGGS AND EJACULATED SPERMS (1999 - 2005)

Age (Yrs)	Treatment Cycles (TC)	Embryo Transfers (ET)	Positive (POS)	Early Pregnancy Loss (EPL)	Clinical Pregnancy (CP)	CP Rate Per ET (%)	No. Of Live Births (LB)	LB Rate Per Cycle (%)	Multiple Birth (MB)	Multiple Birth Rates Per LB (%)
<30	341	282	116	24	92	32.62	80	23.46	23	28.75
30-36	1228	1049	359	89	270	25.74	227	18.49	59	25.99
37-40	585	466	83	18	65	13.95	61	10.43	5	8.20
≥41	176	129	10	4	6	4.65	4	2.27	1	25.00
Overall	2330	1926	568	135	433	22.48	372	15.97	88	23.66

TABLE 4: RESULTS OF ICSI CYCLES USING OWN EGGS AND SURGICALLY COLLECTED SPERMS (1999 - 2005)

Year	Treatment Cycles (TC)	Embryo Transfers (ET)	Positive (POS)	Early Pregnancy Loss (EPL)	Clinical Pregnancy (CP)	CP Rate Per ET (%)	No. Of Live Births (LB)	Multiple Birth (MB)
1999	3	3	1	0	1	33.3	1	0
2000	0	0	0	0	0	0	0	0
2001	8	6	1	0	1	16.6	1	1
2002	20	20	4	1	3	15	2	0
2003	28	27	8	4	4	14.8	4	1
2004	26	27	6	2	4	14.8	4	1
2005	27	24	7	0	7	29.1	7	2
OVERALL	112	107	27	7	20	18.7	19	5

TABLE 5: AGE ANALYSIS OF THE RESULTS OF ICSI CYCLES USING OWN EGGS AND SURGICALLY COLLECTED SPERMS (1999 - 2005)

Age (Yrs)	Treatment Cycles (TC)	Embryo Transfers (ET)	Positive POS	Early Pregnancy Loss (EPL)	Clinical Pregnancy (CP)	CP Rate Per ET (%)	No. Of Live Births (LB)	LB Rate Per Cycle (%)	Multiple Birth (MB)	Multiple Birth Rates Per LB (%)
<30	20	20	4	1	3	15	3	15	0	0
30-36	59	54	14	5	9	16.67	9	15.25	4	44.44
37-40	24	25	8	1	7	28	7	29.17	1	14.28
≥41	9	8	1	0	1	12.5	0	0	0	0
Overall	112	107	27	7	20	18.69	19	16.96	5	26.32

TABLE 6: RESULTS OF ICSI CYCLES USING DONATED OOCYTES AND EJACULATED SPERMS (1999 - 2005)

Year	Treatment Cycles (TC)	Embryo Transfers (ET)	Positive (POS)	Early Pregnancy Loss (EPL)	Clinical Pregnancy (CP)	CP Rate Per ET (%)	No. Of Live Births (LB)	Multiple Birth (MB)
1999	4	4	1	1	0	0	0	0
2000	13	10	0	0	0	0	0	0
2001	12	8	2	2	0	0	0	0
2002	22	18	9	3	6	33.3	6	3
2003	36	45	16	7	9	25.7	7	1
2004	33	49	12	2	10	25.6	8	1
2005	70	65	22	3	19	29.3	15	6
OVERALL	200	179	62	18	44	24.6	36	11

TABLE 7: CONSOLIDATED ICSI CYCLE RESULTS (1999 - 2005)

Year	Treatment Cycles (TC)	Embryo Transfers (ET)	Positive (POS)	Early Pregnancy Loss (EPL)	Clinical Pregnancy (CP)	CP Rate Per ET (%)	No. Of Live Births (LB)	Multiple Birth (MB)
1999	75	64	14	2	12	18.8	12	4
2000	248	194	42	7	35	18.0	28	10
2001	426	321	87	23	64	19.9	54	14
2002	421	335	100	33	67	20.0	56	18
2003	457	394	130	37	93	23.6	80	21
2004	491	431	133	25	108	25.1	93	19
2005	524	473	151	33	118	24.9	104	18
OVERALL	2642	2212	657	160	497	22.4	427	104

TABLE 8: RESULTS OF IVF CYCLES USING OWN EGGS AND EJACULATED SPERMS (1999 - 2005)

Year	Treatment Cycles (TC)	Embryo Transfers (ET)	Positive (POS)	Early Pregnancy Loss (EPL)	Clinical Pregnancy (CP)	CP Rate Per ET (%)	No. Of Live Births (LB)	Multiple Birth (MB)
1999	22	15	3	1	2	13.3	2	1
2000	8	7	3	1	2	28.6	2	0
2001	0	0	0	0	0	0	0	0
2002	2	2	1	1	0	0	0	0
2003	2	2	2	0	2	100	2	0
2004	1	1	1	0	1	100	1	0
2005	5	5	4	1	3	60	3	1
OVERALL	40	32	14	4	10	31.3	10	2

TABLE 9: AGE ANALYSIS OF THE RESULTS OF IVF CYCLES USING OWN EGGS AND EJACULATED SPERMS (1999 - 2005)

Age (Yrs)	Treatment Cycles (TC)	Embryo Transfers (ET)	Positive POS	Early Pregnancy Loss (EPL)	Clinical Pregnancy (CP)	CP Rate Per ET (%)	No. Of Live Births (LB)	LB Rate Per Cycle (%)	Multiple Birth (MB)	Multiple Birth Rates Per LB (%)
<30	6	4	1	0	1	25	1	16.67	0	0
30-36	21	18	8	2	6	33.33	6	28.57	2	33.33
37-40	9	7	5	2	3	42.86	3	33.3	0	0
≥41	4	3	0	0	0	0	0	0	0	0
Overall	40	32	14	4	10	31.25	10	25.0	2	20

TABLE 10: RESULTS OF INTRAUTERINE INSEMINATION (IUI) 2000 to 2005

Years	Treatment Cycles	Clinical Pregnancies (CP)	CP Rate Per cycle (%)	No. Of Live Births (LB)	LB Rate Per Cycle (%)	Multiple Birth Rate Per LB (%)
2000	6	1	16.67	1	16.67	0
2001	5	0	0	0	0	0
2002	4	0	0	0	0	0
2003	7	1	14.28	1	14.28	0
2004	14	0	0	0	0	0
2005	10	2	20	2	20	0
Total	**46**	**4**	**8.69**	**4**	**8.69**	**0**

The Bridge Clinic

Deloitte.

FIG 1: RESULTS OF ICSI CYCLES USING OWN EGGS AND EJACULATED SPERMS 1999 - 2005

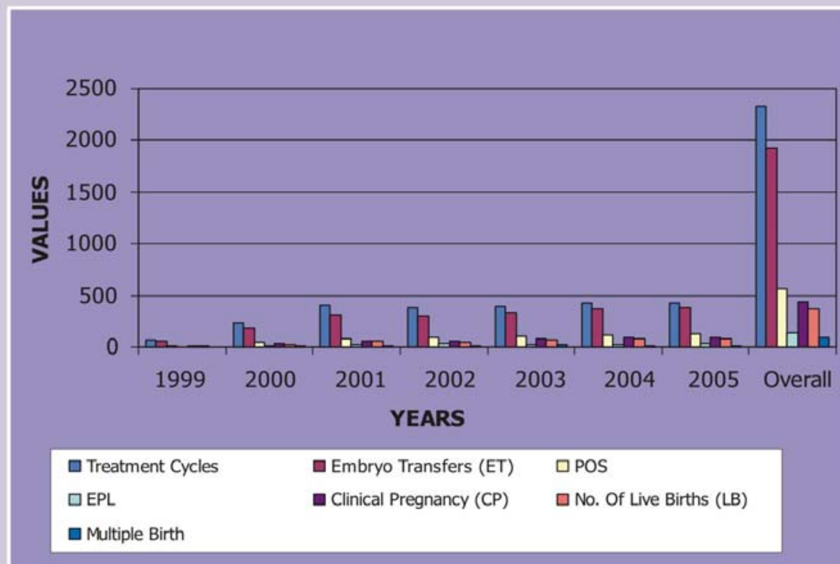


FIG 2: RESULTS OF ICSI CYCLES USING OWN EGGS AND SURGICALLY COLLECTED SPERMS (1999 - 2005)

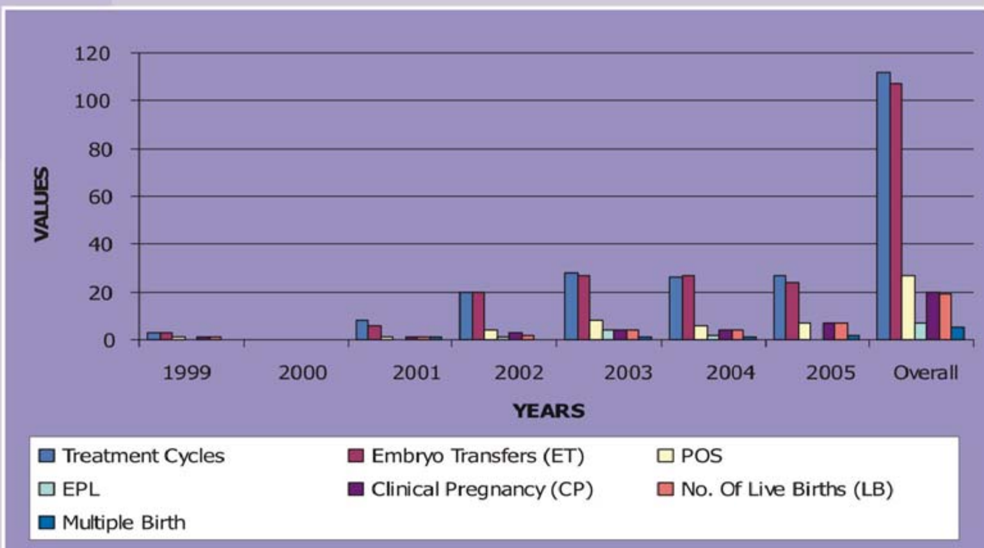


FIG 3: RESULTS OF ICSI CYCLES USING DONATED EGGS AND EJACULATED SPERMS (1999 - 2005)

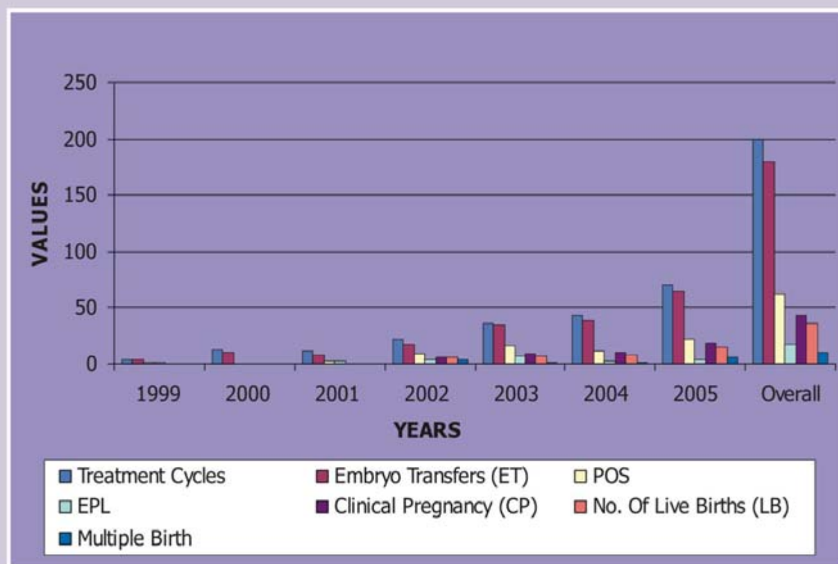


FIG 4: CONSOLIDATED ICSI CYCLE RESULTS (1999 - 2005)

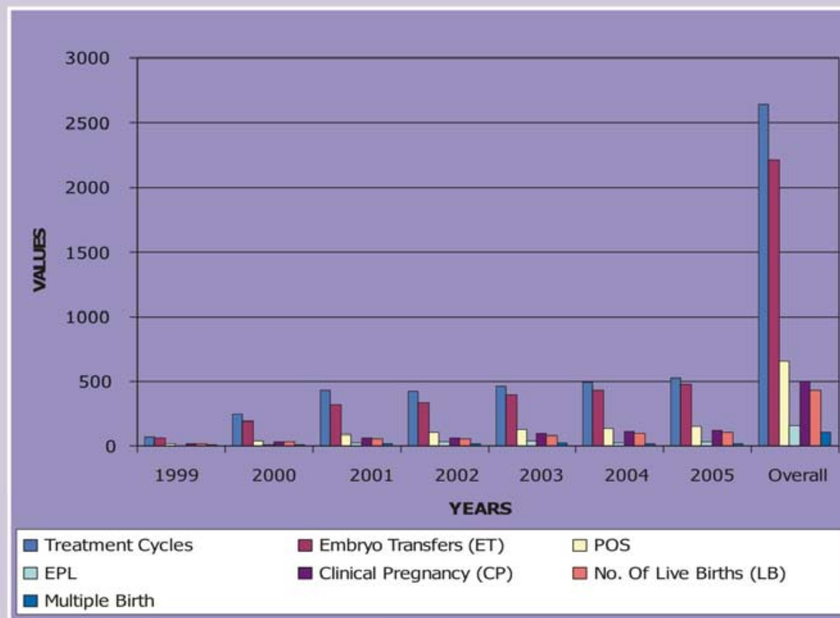


FIG 5: RESULTS OF IVF CYCLES USING OWN EGGS AND EJACULATED SPERMS (1999 - 2005)

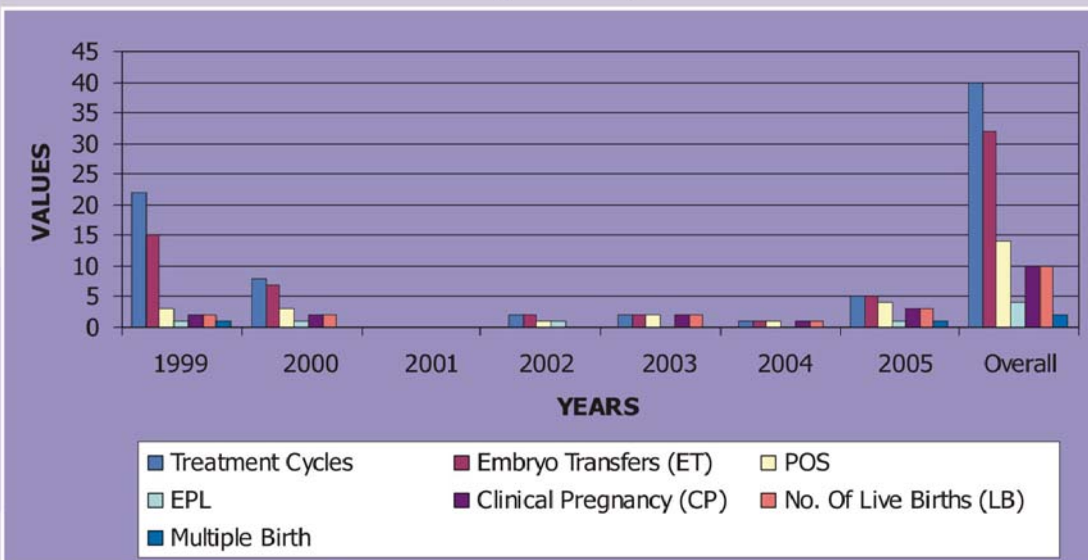
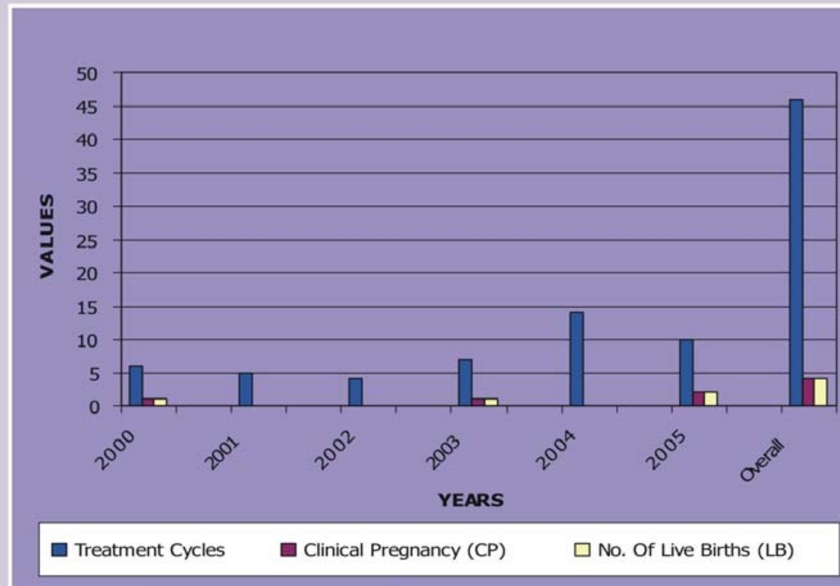


FIG 6: RESULTS OF INTRAUTERINE INSEMINATION (2000 - 2005)



Notes:

1. A cycle is assumed to have begun, once the first injection for down regulation has been taken.
2. A clinical pregnancy is a pregnancy confirmed by ultrasound and demonstrating a beating foetal heart. Biochemical pregnancies are not considered.
3. A live birth is one delivery episode, regardless of the number of babies born.
4. Pregnancy rates with donated eggs usually reflect the rates for the donors.
5. A cycle is assumed to have begun, once the donor has taken the first injection for down regulation.
6. A live birth is one delivery episode, regardless of the number of babies born.

LEGEND

TC Treatment Cycles

ET Embryo Transfers

POS Positive

EPL Early Pregnancy Loss

CP Clinical Pregnancy

LB Live Births

MB Multiple Births

ICSI Intracytoplasmic Sperm Injection

IVF -- Invitro Fertilisation

The Bridge Clinic

Notes