



ASSISTED REPRODUCTIVE TECHNOLOGIES

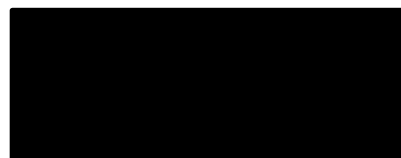
Options for IVF provision in Guernsey and Alderney

Abstract

This report will examine options for potential tertiary IVF (In-vitro fertilisation) provision by the States, taking into account current local Fertility Service provision, and service trends in other jurisdictions. March 2019.

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PURPOSE OF THIS REPORT: OPTIONS FOR PROVISION OF IVF (IN-VITRO FERTILISATION) BY HEALTH & SOCIAL CARE IN THE BAILIWICK

This report will examine options for potential tertiary IVF provision by the States of Guernsey through the Committee for Health & Social Care, taking into account current service trends in other jurisdictions.

Policy G1029 [Fertility Services], ratified by the States as part of the Billet d'Etat II 2002, sets out the current extensive diagnosis and treatment offering available to Guernsey service users who wish to have children, but who approach Primary and Secondary care with fertility issues. The policy complies with NICE Clinical Guidance CG156¹ in its approach to surgical intervention and drug therapy for those who suffer from identifiable conditions which impede fertility.

The Guernsey Fertility Service, staffed by local Obstetricians, offers a full fertility assessment and treatment list, all States-funded, to service users who are referred by Primary Care. This costs Health & Social Care approximately £370,000 per annum².

Once a couple's fertility problems are addressed, and a trial of natural conception post treatment is complete, then couples who still fail to conceive have to decide whether they will either just discontinue their natural efforts, or pursue assisted reproduction/IVF. IVF involves surgically implanting a fertilised embryo into the womb, along with pre-treatment drug therapy, multiple invasive procedures, and other risks to the mother which can at times be painful, both physically and emotionally. In the quest to fulfil their wish for a healthy child, many couples consider this to be a worthwhile undertaking.

The question which has arisen from service user enquiries is whether the States is willing to reconsider financially supporting service users in their use of Assisted Reproduction/IVF.

Delivering Assisted Reproductive Technologies is a speciality apart from Gynaecology and Obstetrics which is not offered on island, because the skill set is not present, and because the cost would make it prohibitive at small scale.

IVF (In Vitro Fertilisation) as a step in assisted reproduction is not funded under Policy G1029 in Guernsey. It has long been considered an unaffordable option for States funding, fraught with eligibility issues, and not necessarily suitable for all infertile individuals. It is very costly – with an average all-in cost of £6,000 for 1 cycle (1 implantation), as well as add-on option costs if chosen by the patient.

Despite this, approximately 40 couples in Guernsey paid privately for cycles of IVF in 2017 in the UK and Europe. There were 60 couples who were treated by Fertility Services in 2017, some of whom went on to conceive naturally, and others who abandoned their attempts. It is felt by clinicians that there is a pent-up demand for IVF on island from those who cannot afford it, were the treatment to be offered at States' expense.

The challenge for commissioners is to weigh the potential benefits of such an offering against all other funding needs within local healthcare budgets.

It is recommended that decision-makers read the attached report in full so that the factual and ethical aspects of IVF are fully considered.

¹ NICE CG156: Fertility Problems: assessment and treatment: <https://www.nice.org.uk/guidance/cg156>

² See Appendix A: Breakdown of fertility workup annual costs

BACKGROUND TO IVF PROVISION IN THE BAILIWICK

Since 1994, the subject of States-funded IVF (In vitro fertilisation) has been debated among clinicians in Guernsey. At that time, it was an emerging technology which had achieved some success but was not widely offered in the UK. The first IVF procedures resulting in live births were completed in both the UK and the USA in 1978.

Guernsey had its first IVF applications in 1994 and 1996, and the requests caused some debate and confusion within the Social Security Authority and the Board of Health. As a technology without a robust history of outcomes data at the time, there was no eligibility process in place for local IVF applicants. All applications were refused by the Board of Health, except for one case which was inexplicably funded directly by the Social Security Authority and was unsuccessful. The Secondary Healthcare Contract 1995 does not mention assisted reproduction.

By the end of 1996, after consideration of UK data for successful outcomes (meaning live births, not pregnancies), and of the potential for a large number of applicants that could lead to spiralling costs,³ it was decided by the Board of Health in Guernsey to not fund any IVF cycles.

The Billet d'Etat II 2002 passed by the States of Guernsey specifically excludes IVF as an eligible treatment for funding.

In 2004, the then-Director of Acute Services delivered a paper to the Guernsey Board of Health, requesting consideration of reinstatement of IVF funding, based on newly-published NICE guidelines based on a very expensive premise (3 IVF cycles and embryo storage) for service provision. The request was rejected. NICE guidance is always the 'ideal scenario', but in the case of IVF, is actually followed to the letter by very few Clinical Commissioning Groups in England.

Since 2013, most NHS trusts have found that following the NICE guideline of providing 3 cycles per patient has become increasingly unaffordable. As of 2019, 85% of NHS England Clinical Commissioning Groups will have moved to funding 1 cycle of IVF per patient lifetime. Some offer preservation of embryos for one year, but this process almost doubles the provision cost and can lead to difficult subsequent decisions about the fate of those embryos.

The States of Guernsey has chosen to retain its policy of no IVF cycle provision throughout the period 2002 to 2019, although supporting procedures such as IUI (Intrauterine insemination) have been funded in the interim. Long term studies have shown IUI to be no more effective than traditional conception practices⁴. In December 2017, the Committee for Health & Social Care discontinued⁵ funding for IUI except for those patients already under a course of treatment, or who for exceptional reasons were not able to conceive naturally, as per NICE guidelines.

It is important to note that the States have from 2002-2019 funded laboratory and imaging diagnostics, medical (drug) and surgical interventions deemed necessary for infertile individuals to become fertile if possible, thereby facilitating natural conception. IVF is a further step only if natural conception fails after surgical and medical interventions.

Guernsey patients who wish to pursue privately funded IVF (In Vitro Fertilisation) and other ART (Assisted Reproductive Technologies) may do so, and the resulting babies are cared for within States provision, including premature births who may require high-cost NICU care in tertiary centres.

It is widely recognised that privately offered ART has become a commercial business, accompanied in some cases by manipulation of complex outcomes data to enhance marketing of services. **This carries huge emotional implications by promoting unrealistic expectations.**

It is clearly important to define "successful outcomes" data as live births which produce a full-term, healthy baby.

³ HSC and ESS committee notes from archives

⁴ <https://www.nice.org.uk/guidance/cg156/evidence/full-guideline-pdf-188539453> pp.202-5

⁵ HSC CMT resolution: December 2017

One IVF cycle: In vitro fertilisation – implantation of one fertilised oocyte [embryo] directly into the uterus. Fertilisation with sperm is done in the laboratory and the embryo allowed to grow for a few days prior to implantation. This bypasses the need for clear fallopian tubes which in some cases can be a cause of female infertility.

IUI: Intrauterine insemination – the simple placement of sperm into the uterus, hoping that fertilisation will occur naturally during ovulation. Long term studies have shown IUI to be no more effective than natural conception methods.

Embryo preservation: An embryo is a fertilised oocyte which can be cryopreserved [frozen] for a period of years, pending future implantation by IVF. Storage by private providers is based on an annual fee, in most cases amounting to £500 per embryo per annum. The only embryo cryopreservation provided under Policy G1029 is for cancer patients whose fertility may be affected for a limited period of time by chemotherapy or radiotherapy.

Fertility drugs: Provided under Policy G1029, the drugs provided by the States are meant to stimulate ovulation, both to encourage natural conception, and in the case of IVF preparation, to stimulate robust production of oocytes in anticipation of artificial insemination. These drugs can only be prescribed by the secondary Fertility Service, so that close patient monitoring by specialists is assured. Unmonitored overdose of some fertility drugs can cause serious health consequences for the patient.

Fertility diagnostics: Various methods of diagnostic imaging which allow the physician to assess the viability of a person's reproductive organs and make decisions for treatment that may remove impediments to natural conception. Health & Social Care in Guernsey spends approximately £370,000 per annum⁶ on such treatments, for women and men.

Post-IVF diagnostics: Various methods of laboratory testing or diagnostic imaging that allow the monitoring of a pregnancy's progress.

HFEA: Human Fertilisation and Embryology Authority: the UK regulatory body for all private Assisted Reproductive Technologies providers, as well as for research and storage involving human embryos. All private UK providers must abide by HFEA guidelines. HFEA does not regulate providers outside the UK. HEFA is very proactive in its offering of red/yellow/green advice to private patients who face a confusing menu of private add-on treatments that are offered along with basic IVF.

NICE guidance: Issued by the National Institute for Health and Care Excellence, the guidelines are meant to present best practice for clinical and social care pathways based on clinical evidence, new technologies, and valuations of economic impact. **It is not mandatory for NHS trusts to follow NICE guidelines.** In the case of IVF, there have been questions raised by most CCG's across England as to the affordability of matching NICE guidelines, as well as suggestions of the influence that private providers have had by representation on NICE committees.

⁶ Appendix A: Costs breakdown for Guernsey Fertility Services

It is estimated that various causes of infertility affect 1 in 7 heterosexual couples in the UK. Since the original NICE guidelines on infertility were published in 2004, there has been a small increase in the prevalence of fertility problems, and a greater proportion of couples now seeking help for their failure to conceive.

Infertility in women – causes

1. Ovulatory disorders (13%)
2. Tubal disease (12%)
3. Cervical mucus problems
4. Fibroids
5. Endometriosis (6%)
6. Pelvic inflammatory disease
7. Side effects of previous medicines and drugs
8. Unexplained infertility (32%)

Infertility in men (37% of cases) - causes

1. Poor quality semen
2. Scarred testicles, from injury, disease or medications
3. Ejaculation disorders
4. Hypogonadism
5. Unexplained infertility

In the UK, unexplained infertility of either partner accounts for around 25% of all cases of infertility. This is where no cause can be identified in either the woman or man.

In about 40% of those cases, disorders are found in both the man and the woman. Uterine or endometrial factors, gamete or embryo defects, and pelvic conditions such as endometriosis may also affect fertility.

About 10% of couples have difficulty conceiving or maintaining a full term pregnancy⁸ despite all efforts.

Given the range of causes of infertility, the provision of appropriate investigations is essential if a couple wish to conceive a child. These investigations include semen analysis; assessment of ovulation, of tubal damage and of uterine abnormalities; screening for infections such as *Chlamydia trachomatis* and for susceptibility to rubella.

Once a diagnosis of infertility has been established, treatment falls into 4 main types:

- **Medical treatment to restore fertility in women and men** (for example, the use of drugs for ovulation induction, facilitating natural conception; or treatment for hypogonadism in men)
- **Surgical treatment to restore fertility in women and men** (for example, treatment of endometriosis or epididymitis, removing barriers to natural conception)
- **Unexplained fertility** where the clear choices are either:
 - **Assisted reproduction techniques such as IVF**, donor, or surrogacy
 - Decision to not pursue any route beyond natural conception

Many couples who experience unexplained infertility choose IVF as their next step. This procedure is rapidly becoming unaffordable for most couples, and for NHS commissioning groups who try to follow NICE guidelines, but who wish to commission private services for publicly-funded patients. More than 50% of IVF procedures are now carried out by private commercial providers in the UK. Since 2016, there has been a rising tide of criticism in the UK press with regard to advertising by these providers, where some have been observed to offer false hope by reporting exaggerated or ill-defined success rates, and add-on “extras” of little or no evidence-based clinical value.

⁷Data from HFEA <https://www.hfea.gov.uk/>

⁸Centres for Disease Control <https://www.womenshealth.gov/a-z-topics/infertility>

Offshore IVF providers are also numerous, and although their costs are often half that of the UK providers, the States has no control over clinical governance, clinical quality, or creation of risky situations such as multiple pregnancies. A study by the University of Manchester, reported in BMJ Open⁹, found that a lack of binding guidance for private IVF providers is supporting misleading advertising leading to false hope.

CURRENT IVF PROVISION: NHS ENGLAND CLINICAL COMMISSIONING GROUPS

NICE guidance as currently written, recommends 3 cycles per patient to age 40, and 1 cycle per patient beyond age 40. This guidance is due for review in 2020.

The **high cost** of IVF to the NHS, coupled with a **statistically low live birth rate** in some age groups, has come full circle. The higher-offering CCG's are all currently conducting consultations¹⁰ with regard to a 1 cycle offering, mostly driven by 'postcode tourism' and a national call for transparency and fairness. Strict eligibility criteria with regard to age, existing children, prior sterilisation, and in some cases, means testing, are applied by each CCG.

In 2019, among **200 Clinical Commissioning Groups in the UK**.¹¹

| Year CCGs / | 0 IVF cycles | 1 IVF Cycle | 2 IVF Cycles | 3 IVF Cycles |
|----------------------|---------------------|--------------------|---------------------|---------------------|
| 2018 pending changes | 6% | 85% | 5% | 4% |
| 2017 | 4% | 61% | 23% | 12% |
| 2016 | 2% | 60% | 22% | 16% |
| 2015 | 1% | 57% | 24% | 18% |
| 2014 | 1% | 52% | 29% | 18% |
| 2013 | 3% | 49% | 24% | 24% |

⁹ <https://bmjopen.bmj.com/content/7/1/e012218>

¹⁰ The Oldham NHS trust, where the world's first IVF baby was born in 1978, has initiated a public consultation in October 2018 to move back to funding only one cycle of IVF. They have found NICE guidance to be financially unsupportable.

¹¹Independent data: <http://www.fertilityfairness.co.uk/number-of-ccgs-offering-3-ivf-cycles-has-halved-since-2013/>

HFEA DATA: OVERALL UK IVF PROVISION IN 2016¹²

| Age of female | % of all cycles |
|---------------|-----------------|
| <35 | 42% |
| 35-37 | 23% |
| 38-39 | 14% |
| 40-42 | 14% |
| 43-44 | 4% |
| >44 | 3% |

- 48% of NHS trusts do not offer IVF to age 40+
- 10% of NHS trusts do not offer IVF to age 35+
- Several NHS trusts are actively consulting on a limited offering to the 30-35 age group only

Other relevant HFEA data for IVF cycles:

| Relationship status | Cycles | % of all cycles |
|-------------------------|--------|-----------------|
| Heterosexual couples | 64903 | 95% |
| Same sex female couples | 1683 | 3% |
| Single woman/no | 1272 | 2% |
| | | |
| | | |
| Egg and sperm | Cycles | % of all cycles |
| | | |
| Own eggs/own sperm | 4306 | 6% |
| Donor eggs/own sperm | 3000 | 4% |
| Donor eggs/donor sperm | 924 | 1% |

- Multiple births: the trend is toward singleton births, showing a dramatically lower rate of multiple births since 2010. This is largely due to clinical guidelines recommending single implantation as a safer approach.
- Use of frozen embryos: data shows that the largest user group for frozen embryos is >44 years.
- Total surrogate births in the UK (2016) = 79.

¹² <https://www.hfea.gov.uk/media/2705/audit-and-governance-committee-agc-meeting-papers.pdf>

Policy G1029 - Fertility Services is very clear as to which elements of the fertility pathway are States-funded. It was first passed by the States in 2002, and has been subject to minor clinical revisions in 2017 and 2018.

Policy G1029 clearly follows NICE clinical guidance CG156¹³ for the diagnosis and treatment of infertility. UK-wide data indicates that Guernsey is no different from other jurisdictions in its offering to infertile couples wishing to solve barriers to natural conception that are solvable through surgery and drug therapy. The next step for these couples is either natural conception, or assisted reproductive technologies (including IVF) at their own expense.

IVF (In Vitro Fertilisation) is not currently funded in Guernsey, except in rare cases where fertility preservation is warranted when a patient is anticipating certain cancer treatments. IVF is available in tertiary centres in the UK and elsewhere on a privately-paid basis. However, Policy G1029 does provide substantial continuing local diagnostic and medical support during pregnancy to those who approach the Fertility Service and who have proceeded to private IVF.

WHAT GUERNSEY FERTILITY SERVICES **DOES** PROVIDE TO ALL SERVICE USERS

Currently, the Guernsey system provides significant value to couples who present with an inability to conceive.

- ✓ It is estimated¹⁴ that over £370,000 was spent in Guernsey in 2017, providing care directed by the Secondary Care fertility service and run by Gynaecologists & Obstetricians employed by MSG.
- ✓ Approximately 60 couples were provided with a range of States-funded, thorough laboratory diagnostics, diagnostic imaging, counselling, surgical intervention if needed, and fertility drug therapy to induce ovulation.
- ✓ This offering effectively provides all the services that one might find in a private provider price list under the headings of consultation and tests, investigations, surgical interventions and screening.

Specifically, the Guernsey Fertility Service offers the following under States funding:

- ✓ Investigations of infertility to provide a definitive diagnosis, thereby enabling couples to consider their management options.
 - Tests which may be ordered in Primary Care prior to referral to a local Fertility Specialist
 - Tests and expectant management¹⁵/counselling, done under supervision of the Fertility Clinic, including lifestyle modification and nutritional supplementation to support healthy pregnancy.
- ✓ Medical management (drugs) for male infertility
- ✓ Surgical management for male infertility
- ✓ Medical management (drugs) for ovulatory disorders
- ✓ Surgical management of female infertility, including endometriosis
- ✓ Exceptional circumstances in which intrauterine insemination may still be offered (disability)
- ✓ Preservation of fertility for patients undergoing cancer treatment
- ✓ Preservation of fertility for patients for other indications, considered on a case-by-case basis by IFR
- ✓ Travel funding for couples seeking private IVF in the UK (verified by off island)¹⁶

¹³ <https://www.nice.org.uk/guidance/cg156>

¹⁴ Appendix A – Breakdown of Fertility Service costs 2017 in Guernsey

¹⁵ **Expectant management:** A formal approach that encourages conception through unprotected vaginal intercourse. It involves supportively offering an individual or couple information and advice about the regularity and timing of intercourse and any lifestyle changes which might improve their chances of conceiving. It does not involve active clinical or therapeutic interventions.

¹⁶ This is allowable under the 1990 Travel Grant legislation per Employment and Social Security

WHAT GUERNSEY DOES NOT PROVIDE UNDER POLICY G1029

The following elements of the fertility pathway are not funded by Health & Social Care in Guernsey:

1. Diagnostics, tests, procedures and treatments which are on NICE's do-not-do list
2. Any artificial means of insemination
3. Reversal of sterilisation, including semen analysis following reversal
4. Surrogacy
5. Privately arranged fertility treatments

PRIVATE IVF PROCURED BY GUERNSEY RESIDENTS IN 2017: DATA

Many of the Guernsey patients whose diagnosis is "Unexplained Infertility", meaning that no physical cause is found to be impeding natural conception, then go on to seek private IVF procedures at clinics in the UK and elsewhere.

Off island data for 2017 shows that 30 couples applied for travel funding specifically for private offshore IVF consultations. Most were directed by MSG consultants toward a familiar provider [REDACTED] but in about 10% of cases, treatment was sought elsewhere in the UK, and one patient went to a Spanish clinic.

Guernsey Fertility Services offered, per Policy G1029, initial infertility workups and interventions, for most patients who later sought private IVF from 2015-2018. Guernsey Fertility Services did maintain a link with a private provider, [REDACTED] [REDACTED] representatives come to the island monthly to interview prospective patients at MSG offices. Many of these private patients who sign on with [REDACTED] continue to receive care from local Gynaecologists & Obstetricians before, during and after their 2017 IVF procedures, through the PEH Outpatient department in the form of health checks, imaging, and diagnostics. Five pending singleton births arising from private IVF initiated in 2017 are currently being monitored by local Obstetricians.

It is not known how many other couples simply sought private infertility services in the past five years, without any funding or preliminary work from the States.

| Female patients seen in 2017 - PEH Outpatients - marked as "private IVF" | | | | | | | |
|---|-----------|-------|-------|-------|-------|-----|-----------------------------------|
| Individuals undergoing private IVF who are receiving local support from O&G team | | | | | | | |
| | Age group | | | | | | Total in-year episodes of care |
| | <30 | 30-34 | 35-37 | 37-39 | 40-45 | >45 | |
| 2015 | 1 | 13 | 10 | 9 | 10 | 2 | 117 |
| 2016 | 4 | 12 | 12 | 6 | 8 | 1 | 152 |
| 2017 | 2 | 15 | 5 | 5 | 12 | 1 | 108 |
| 2018 (10 mo) | 5 | 9 | 8 | 5 | 10 | 1 | 71 |
| | | | | | | | 448 |
| Episodes per age group | 12 | 49 | 35 | 25 | 40 | 5 | |

Notes:

1. Analysis of patient URNs indicates that there were **109 patients** in total coded as "IVF private" over the 4 year period 2015-2018 in the above data, all of whom must have secured some private IVF provision during that period.
2. It is not clear whether these patients had private insurance which was charged by HSC for any of the diagnostic or imaging work resulting from these OP appointments.
3. It is not known how many other local patients paid privately for diagnostic and imaging work off island or in foreign clinics.
4. The outcomes data for the private IVF patients were found by tracing through TRAK.

The benefit of providing States funding to couples does include the ability to control the quality of services acquired, particularly to have some suasion by advice over **the number of multiple/complex premature births**, which ultimately become the States responsibility to fund and care for. However, all patients are free to acquire services in differently-regulated jurisdictions where IVF practices do encourage multiple births, so this will always be a risk.

NICU costs for IVF babies are carried by the States. As mentioned above, the costs of IVF babies are not separately accounted for by the Maternity Service, since IVF information is often not divulged by the parents.

| Guernsey private IVF patients 2017 with off island travel paid ESS | | | | |
|--|-----------|--------------|--------------|---------------------|
| Agegroup (women) | Patients | No pregnancy | Positive Hcg | Live births in 2018 |
| <30 | 3 | 1 | 2 | 1 |
| 30-34 | 8 | 5 | 3 | 1* |
| 35-37 | 5 | 2 | 3 | 3 |
| 38-40 | 1 | 0 | 1 | 1 |
| >40 | 7 | 7 | 0 | 0 |
| Total | 24 | 15 | 9 | 6 |

It is evident that the results experienced by this sample group may be statistically similar to results across the UK, if the expected births in 2018 do result in positive outcomes. The results are taken directly from patient records where the URN was matched with the travel grant number.

*One live birth resulted from IVF completed in 2017 in [REDACTED] after 5 cycles. The rest were conceived in domestic UK clinics. Not every patient record shows the number of attempted IVF cycles undertaken to achieve a live birth. Prenatal scans done locally indicate singleton births in all the above cases.

**These are not all the private IVF patients from Guernsey in 2017; only listed are those who claimed travel expenses.

Outpatient clinic records show that there have been a total of 109 private IVF patients from 2015-2018 who received 425 episodes of care from local Obstetricians and Gynaecologists, during their period of private IVF care off island.

INTERVIEWS WITH LOCAL (PRIVATE) IVF CANDIDATES: ETHICAL AND EMOTIONAL IMPLICATIONS

Pursuing IVF treatment can have a tremendous impact on any couple: it is a very demanding physical process, with far-reaching effects on their psychological well-being, their relationship, their social environment. Candidates cited the following as their clear recollection of the experience:

Emotions and expectations can run high:

The process, which involves a rigorous schedule of self-injection of hormones, anaesthetics and clinical procedures, can leave a woman exhausted and disheartened, as well as causing mood swings that affect her relationships. This, along with the failure that often accompanies an IVF cycle, has resulted in some patients stating that they “wished they had never embarked on the journey”. Men who are identified with fertility problems frequently experience anger, depression and anxieties which have a profound effect on their well-being.¹⁷

- For the minority of local candidates who were successful (meaning a healthy baby) found that “all the pain was worth it in the end” but that they “wouldn’t choose to do it again”.
- All successful candidates expressed dismay at what a negative result might have done to their psychological well-being.
- The unsuccessful candidates expressed a range of outcomes: periods of mourning, broken relationships, mental health issues, long periods of adjustment and acceptance, finances never recovered.
- Many mentioned people they knew who had not had IVF due to unaffordability; this situation also created the negative emotions as listed above.
- Some stated their belief that IVF should be available to local candidates when they are at the most fertile age, since many cannot save up for the procedure when they are <35.

For the above reasons, it would be incumbent on the local Fertility Service to ensure that each candidate receives **adequate counselling and realistic information** prior to IVF. It may be that such counselling needs to be acquired as part of tertiary services. An established link with one tertiary provider would be essential to ensure patients are not on their own.

Tertiary Services:

- IVF and other Assisted Reproduction Technologies have evolved and improved since inception in 1996 and the commercial reality makes it a business affected by profit motives. This has meant that the inevitable influence of marketing has become a daily part of the ART/IVF offerings available in the UK.
- Candidates who sought private IVF faced confusing and expensive choices that in most cases, left them feeling they had overspent for unnecessary extras, no matter what the outcome.

The UK regulatory agency, HFEA, has tried to mitigate patient confusion by instituting a program of ratings for “**add-on**” **services** offered by private clinics which are marketed to clients as a way of enhancing their chances of conception. As of early 2019, virtually none of these services are rated as “green”, meaning that **none of them are based on success in evidence based clinical experience**.

- The issue of embryo cryopreservation was also cited – where the ovarian stimulation required to produce oocytes then means that multiple embryos are fertilised – and only one is chosen for implantation. The choice then arises as to the fate of the other embryos. Clients must pay substantial preservation fees (£5,000 over ten years per embryo). Service users spoke about the additional period of mourning triggered by the decision to discontinue cryopreservation.

¹⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4700889/>

COST OF THE CURRENT GUERNSEY FERTILITY SERVICE

To deliver the services mandated in Policy G1029¹⁸ "Fertility Services", the States paid out locally in 2017:

- A total annual expenditure of approximately £370,000 to support eligible candidates through diagnosis and treatment for fertility problems via the Fertility Service, run by local Gynaecologists & Obstetricians.

The above consisted of:

- £ 16,560 for laboratory tests ordered in Primary Care
- £ 14,600 for laboratory tests ordered in Secondary Care
- £ 35,889 in medical imaging scans ordered in Secondary Care
- £198,948 in surgical procedures for enhancement of fertility
- £ 23,100 for Intrauterine Insemination workups [discontinued per Policy G1029 revision, December 2017] In

addition, ESS supported the following:

- £ 4,500 to support couples' travel to obtain private IVF in the UK and Europe
- £ 75,657 in fertility medications ordered by Fertility Services

The total patient cohort who accessed the Fertility Service in any way, on island, was **60 couples** in 2017. This equates to an average expenditure of about **£6,300 per couple** to assess, intervene and treat symptoms of infertility.

No IVF implantation was funded from 2002-2018 for any island residents, although scans and laboratory tests during the IVF period were States paid if done on island by MSG, and mothers and babies were treated as per States provision afterward.

It is felt by clinicians both in Obstetrics and in Maternity that there would be a significant pent-up number of island residents who, if offered IVF, would likely present themselves as candidates. This could result in significant early workload and the resultant resource requests for local Fertility Services in the first couple of years of implementation.

COST OF CARING FOR COMPLEX BIRTHS – NICU / OFF ISLAND

The HSC Maternity Service does ask patients whether the babies they deliver were originally conceived by any form of ART, but not all patients provide this data.

There is a generally held belief that private IVF resulting in multiple, complex births ends up as a cost to the Guernsey system when premature and ill newborns are cared for at a tertiary NICU centre in the UK.

The off island medical cost (including NICU) in tertiary centres for premature infants 2014-2016 was: **£226,574**.

Additional costs for transport & medics for the same time frame and patient cohort was: **£112,735**.

It is possible that *some of the above* arose due to multiple births created by private, offshore IVF providers who are not regulated by HFEA.

¹⁸ See Appendix A: Detailed costings of Fertility Services provision in 2017

COSTS: PRIVATE IVF IN THE UK

The cost of funding one cycle of IVF at a private UK provider ranges from £5,000 upward. IVF does not just involve embryo implantation; there are pre- and post-procedure scans, oocyte retrieval, and embryo fertilisation in the laboratory to be funded. As it stands, some private providers will accept local Guernsey laboratory and imaging results, but this is not mandated by any authority.

Additional costs for embryo cryopreservation, transfer, and subsequent implantation approach £7,000, and this incurs an additional annual commitment per client to retain the cryopreservation. This, coupled with the emotional impact of time-limited financial support raises issues that could involve dispute between the States and service users if cryopreservation were to be funded.

3 cycles of IVF which include embryo cryopreservation, have been shown to cost an average couple a minimum of £15,000 in out of pocket expenses¹⁹ if done at a commercial private facility in the UK. **Some offshore facilities may charge less, but are not regulated by HFEA.**



RISKS: PRIVATE IVF

- It is widely agreed that the single largest risk of IVF is the effect of **multiple-child pregnancy** and birth on the health of both mother and child. The reality is that many offshore IVF providers will implant multiple embryos, hoping to increase the success rate, but instead having the effect of causing a high risk pregnancy.
- Anecdotally, a small number of Guernsey residents are utilising the services of offshore IVF providers.
- The extensive menu of choices offered by private providers (some unnecessary) can be overwhelming for couples who already face an emotional situation.
- If the States supported a recommended provider offering a limited but effective “package” price for one cycle, it could lessen the risk of leaving clients on their own to discern what procedures are necessary.

Any option to provide HSC funding for IVF will necessitate the **scoping, negotiation, purchase and monitoring of tertiary private services by an HFEA-regulated provider**. HSC, in retaining its responsibility for the aftercare of mothers and babies, would benefit from involving an HFEA-regulated provider. Guernsey had three sets of twins born at PEH in 2017, whose care was continued in the [REDACTED] NICU at Guernsey expense, but it is not known if they were IVF children.

¹⁹ <https://www.conceptfertility.co.uk/fertility-treatments/ivf-treatment/ivf-3-cycle-package-costs-included-or-excluded/>

²⁰ From HFEA guidance 2017

SUCCESS RATES FOR IVF BY AGE GROUP

Success rates for IVF depend on many factors, including the skill of the clinician performing the procedure, the infertility diagnosis, and the age of the woman undergoing the procedure. This last factor—the woman’s age—would seem to be especially important, given the data which exists.

Success rates seem to be reported differently, depending on the vested interest of the reporting body. Some do not define what “success” means and it is often difficult to directly compare data. The following were the *least biased* data sets available.

NHS data (UK national) for the chances of having a full term, normal birth weight baby as published:

Between 2014 and 2016 the chances of NHS-funded IVF cycles²¹ resulting in a live birth was:

- 29% for women under 35
- 23% for women aged 35 to 37
- 15% for women aged 38 to 39
- 9% for women aged 40 to 42
- 3% for women aged 43 to 44
- 2% for women aged over 44

The **Centres for Disease Control**²² (USA – independent entity from commercial providers) separates success rate data for fresh and frozen embryos. The overall chance of having a full term, normal birth weight baby with fresh embryos per IVF cycle (in the United States), after preliminary fertility treatment:

| | Age of woman | | | |
|----------|--------------|-------|-------|------|
| | <35 | 35-37 | 38-40 | >40 |
| National | 21.3% | 17.0% | 11.1% | 4.1% |

While it is possible to find a much wider range and claims of success for cycles of IVF, it was felt that most of the entities reporting wildly optimistic IVF results also could be linked to vested commercial interests. Many commercial clinics quote success rates in terms *other than* viable full term births.

HFEA (Human Fertilisation and Embryology Authority in the UK) gathers data from commercial providers in the UK whom it regulates. It is clear from HFEA public statements that they consider the commercial provision of IVF in the UK to be confusing for private patients making their own choices. Commercial providers offer add-on procedures at considerable cost to clients with little or no proof of efficacy. For this reason, HFEA has assumed the task of full auditing and rating each add-on procedure as red/yellow/green, based on credible research results, so that consumers can use the guidance. At present, HFEA rates no add-on procedure as ‘green’ (which would indicate evidence-based proof of effectiveness).

²¹ <https://www.nhs.uk/conditions/ivf>

²² Centres for Disease Control, *Assisted Reproductive Technology Fertility Clinic Success Rates Report, 2015*
<https://www.cdc.gov/art/artdata/index.html>

OPTIONS FOR IVF PROVISION IN GUERNSEY

Choosing options beyond the current policy (0 cycles of IVF, no funding of donor or surrogacy provision) will require some carefully considered eligibility decisions, based on data. Widening of criteria leads to expanded numbers of candidates and therefore higher overall cost. Every option requires ethical, safety, and fairness decisions that must align with existing States policies, including G1033 Public Health Prioritisation, and pending Discrimination policies being developed by Employment & Social Security.

This is why it is necessary to be clear that the brutal reality that IVF costs as mandated by NICE guidance have created a huge financial burden for Clinical Commissioning Groups in England. In most cases, costs appear to have been escalated by commercial manipulation, lack of clarity for service users, and inattentive regulation. This reality has prompted the current moves by most English CCG's to severely limit IVF funding, despite the intransigence of NICE guidance.

It is important for policy-makers to know that the extensive "success" data published online by commercial providers and in some cases, by industry groups, is often skewed to headlines around random data which does not at all fit in with standard definitions of what constitutes a good outcome.

Simply choosing to fund "1 cycle of IVF" needs to be very closely defined in terms of what is included as eligible treatment. If not, then situations can escalate into unforeseen complications.

Other considerations:

- It is essential to define success (live, healthy births) to accurately quantify the economic benefits of supporting local population growth.
- There are potential psychological, employment, and human costs to any unsuccessful fertility attempt.
- If funding of IVF were to be considered, it is essential to do it in a way that promotes the **best possible chances of success**. It is important to recognise the economic barriers to IVF that prevent women of ideal fertile age from conceiving at the ideal time.
- Fertility rapidly declines as a woman approaches her mid 30's, thus the incentive to consider lower age brackets for inclusion in funding.
- Fertility does not disappear completely until menopause, and so it is important to note potential age discrimination in provision of funding.
- It is a fact that the drug stimulation provided prior to an oocyte collection (the IVF event) will often trigger the production of multiple viable oocytes. These become embryos during the fertilization process, but then **the choice as to retention, storage and future implantation carries a cost and timing element which can be highly emotionally charged.**

In considering **eligibility for IVF funding**, then the following factors and suggested requirements could be taken into account:

Age considerations from independent data:

- The optimum age for conception by females is 26-35. Success rates decline steadily in older age groups.
- Consideration: Some islanders simply cannot afford IVF at an age when their chances of success are best.

Expectant management: attempts at natural conception prior to embarking on medical intervention.

- Completion of expectant management for 2 years is advised.
- Mandatory completion of local fertility workup to ensure safety.
- A wait period allows couples to plan and consider whether the experience of IVF is suitable for them.
- Counselling by specialist IVF practitioners prior to undertaking IVF.

Underlying physical and mental health considerations:

- Excessive BMI (Body Mass Index) in either partner has been shown to impact fertility (limitations advised);
- Women suffering from some conditions do benefit from interventional procedures²³ and are often subsequently successful by natural means if given adequate time lapse.
- Fertility treatments and medications are not without risks to the person's health.
- There are huge emotional considerations around potential failure and creation of false hope.

Residential/income/circumstantial eligibility:

- Length of residency on island to avoid postcode tourism.
- Possible means-testing of family income levels to determine eligibility (current Jersey policy limits family income to £40,000 but they have never had a candidate in this category).
- Pre-existing children in the household – always an exclusion in the UK.
- Reversal of prior sterilisation in either partner is not funded in other jurisdictions.

Equity/equality/social considerations:

- Equity considerations in funding IVF for same-sex couples will likely add costs such as IUI and donor sperm/eggs.
- Cryopreservation and storage of embryos and oocytes (potential legal and moral issues) should the States become involved in this, or should patients to be required to pay for storage.
- HFEA-regulated provider, if commissioned, would ensure parent compliance with child standards.

Economic considerations:

- An arrangement with a tertiary (UK) provider will increase the workload of the local Fertility Service and off island teams, which would need additional resource to manage the interface with tertiary providers, counsel patients, and deal with post-IVF complications.
- Costs could be substantial unless eligibility is restricted, or if a single universal grant option is chosen.
- Must be evaluated against all other credible health interventions needed by islanders.
- QALY scores, if only applied to successful births, are high, but mitigated by overall success rates.

²³ Treatments and drug therapy funded by Guernsey Fertility Services

Already included for States funding under this option:

- **Current provision of Fertility Services (surgical and medication) as per Policy G1029 to achieve diagnosis of unexplained infertility would continue to be available to all service users.**
- **Travel costs to have private IVF procedures in the UK and Europe.**

Additional eligibility for a States-funded IVF cycle would require a decision on each item in this list:

1. Eligibility criteria as set by HSC Committee (with advice from local medical specialists)

- Age range limitation (dictates number of candidates);
- BMI limitation for both partners (female and male = 18.5-30)²⁴
- Both partners resident of Guernsey for at least two years (to allow for monitoring natural conception));
- No previous attempts at IVF can have occurred in any jurisdiction;
- Single embryo implantation only eligible for funding;
- No funding to reverse prior sterilization of either partner;
- Candidates must have undergone thorough infertility assessment by Guernsey Fertility Service;
- Candidates must be deemed to be clinically suitable for IVF in the opinion of a local Fertility specialist in secondary care;
- IVF Follow up, wellness appointments, and imaging should be conducted by Guernsey doctors except in unusual circumstances;
- Couple (or single parent) must pass HFEA child standards assessment;
- Commissioners could consider applying means-testing for financial support;
- Embryo cryopreservation, donor, and surrogacy costs not eligible for States funding;

2. The proposed commissioned offering: stipulation that a funded IVF cycle must be provided by a designated provider with whom HSC will have negotiated arrangements and limitations on eligible tertiary services. Management of this arrangement may increase the workload of the local consultants sufficiently to require a fertility nurse/counsellor.

3. The proposed level of funding: a specific £ cap on funding could allow candidates to self-fund optional extras.

Benefits:

- ✓ One cycle of IVF would not be out of reach for any qualifying islander;
- ✓ **Implantation of one embryo only** would eliminate multiple births deemed to be more risky;
- ✓ There is already a formal link between MSG and [REDACTED] with whom a package price may be straightforward to arrange;
- ✓ If the service user wished to access extra services outside the package definition, that would be self-funded;
- ✓ Local monitoring and imaging during pregnancy and after birth to be done on island;

Risks:

- ✓ Any exclusional criteria could be subject to political or legal challenge;
- ✓ Temptation for patients to rush into IVF without proper expectant management;
- ✓ Stipulation of one embryo implantation could raise concerns about the fate of other embryos created in the cycle.
- ✓ Cost of provision could be open-ended since the number of candidates is not precisely predictable.

²⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3478419/>

COST ESTIMATES – ALL OPTIONS

The following cost estimates are based on a negotiated package price²⁶ with a tertiary provider for simple IVF, without “add-ons” or continuous follow up off island. In the £6,000 per cycle estimate, allowance has been made for the services of a counsellor, travel to a tertiary centre for couples, and the sperm collection, laboratory and implantation work necessary for one complete IVF “cycle”.

[REDACTED] as an example, lists IVF implantation alone as costing £3,915, separate from a long list of other add-on features of IVF that can run up the bill considerably.

The total costs estimated below do not include the £370,000 per annum already funding Fertility Services locally.

Any adjustment to eligibility criteria would change the total demand number in any scenario. These are examples:

OPTION 1: NO CHANGE TO CURRENT FUNDING FOR IVF (NO CYCLES)

This option would retain the status quo, with a full local Fertility Service per Policy G1029 in place for all islanders.

The cost of IVF would be borne privately by those who choose to pursue it. All other care, as described in the report, would continue to be available to expectant mothers and their babies, with no regard to how the pregnancy was conceived.

OPTION 2: PROVIDE 1 CYCLE OF IVF -- MEANS TESTED

Patient activity >20-30 cycles (this demand would vary depending on means limitations imposed on eligibility criteria)

@ £6,000* = **£120,000 – £180,000 per annum**

***does not include cost of current local Fertility Services to treat causes of infertility.**

OPTION 3: A UNIVERSAL, LIMITED GRANT FOR IVF FOR A MANDATED TERTIARY PACKAGE

Patient activity 50 – 70 cycles

@ £4,500 per cycle = **£225,000 – £315,000 per annum**

Simply provide each qualified service user with a set grant amount to be paid directly to an agreed tertiary package, as long as service users accept the responsibility to privately fund any amounts spent beyond the grant.

As an example, a grant of £4,000 + travel per user would cover the main cost, i.e. the IVF implantation, and the service user would have to budget for any ancillary costs. However, the grant would likely make one cycle a possibility for most people without creating life-changing financial imp

OPTION 4: PROVIDE 1 CYCLE OF IVF UNIVERSALLY (AGES 26 TO 42)*

Patient activity >50 – 70 cycles (an initial surge of demand)

@ £6,000 = **£300,000 -- £420,000 per annum**

Same criteria as Option 1, except that means testing does not apply

*based on Guernsey patient activity, reducing eligibility to <35 age group would create a patient cohort of 30, but would be likely subject to claims of age discrimination.

OPTION 5: PROVIDE 1 CYCLE OF IVF AND ONE LIMITED-TIME EMBRYO CRYOPRESERVATION

Patient activity >50 – 70 cycles & vitrification (cryopreservation of embryos)

@ £5,000 & £7,000 = £12,000 x 50 = **£600,000 or x 70 = £840,000**

Same criteria as Option 3, but includes embryo cryopreservation for a defined time period

Benefits:

- Embryos available for further cycles (if service user able to pay privately for cycles);
- Does reduce patient risk in future cycles because ovarian stimulation could be bypassed.

Risks:

- Service users may not be able to afford more cycles, despite having preserved embryos - - this could lead to complex social issues and disputes;
- Couple must have firm agreements around ownership and fate of embryos.
- Decision about embryos will at some point become another emotional milestone for patients.
- Very costly option for the States because it involves annual recurring fees for storage.

OPTION 6: MATCH GUERNSEY PROVISION TO NICE RECOMMENDATIONS

This option would provide 3 cycles of IVF to 31 women under 40 who meet eligibility criteria, and 1 cycle to 18 women over 40. If the proportionate ages of the sample 2017 private IVF group are used, this would equate to an annual cost in the region of:

63% women under 40 = 31 candidates @£6,000 per 1 cycle x 3 = £558,000

37% women over 40 = 18 candidates @£6,000 per 1 cycle = £108,000

If embryo cryopreservation were included, the cost would be £350,000

Total estimate for just Guernsey IVF provision per NICE guidelines: **£1,016,000**

Total estimate for IVF and Fertility Service per NICE guidelines: £1,386,000

Option 5 assumes that costs for donor sperm or eggs, surrogacy, and other exceptions per Option 2 would be payable by patients.

OPTION 7: LOCAL OPTION FOR IVF PROVISION

Setting up a local IVF and embryology service.

The staffing and clinical governance requirements for a local service are financially prohibitive for a jurisdiction where the maximum number of candidates per annum would not likely exceed 60.

As a non-HFEA-regulated jurisdiction, a commercial provider in Guernsey *could offer* anonymous donor services [i.e. unregistered donor sperm, as in Scandinavian practice]. It is unlikely that such a service would be able to compete with offshore (European) providers who have more substantial local patient activity.

The most expensive components of such a service would include an embryologist, embryo and sperm storage facilities, HFEA assessments and audits, and licenses to import liquid nitrogen. Therefore, the only option for provision of States-funded IVF and embryo storage are with private, HFEA-certified tertiary providers.

Policy G1029 - Guernsey - Breakdown of fertility workup annual costs
Services which Guernsey patients currently receive in Fertility Services

| HSC G1029 (Fertility) | NICE guide CG156 | Provider | NICE-recommended fertility workup - per Policy G1029 | Procedure recommended | Purpose | Cost HSC per PT | Patient activity 2017 | Contract patients | Private patients | System costs per policy G1029 |
|-----------------------|------------------|----------------------------------|--|--|--|-----------------|-----------------------|-------------------|------------------|-------------------------------|
| 1.2.2 | | Primary | Blood test to measure serum progesterone to establish fertility | Serum progesterone on day 21 of 28 day cycle | Determine if ovulation has occurred in present cycle | £ 50 | 60 | 60 | n/a | £ 3,000 |
| 1.2.2 | 1.3.13 | Primary | Chlamydia trachomatis screening (men and women) | Urine sample | If positive, woman & partner treated & contacts traced | £ 70 | 120 | 60 | n/a | £ 8,400 |
| | 1.3.12 | Primary | Cervical screening | Cervical screen | Per States programme | £ 50 | 60 | 30 | n/a | £ 3,000 |
| 1.2.5 | 1.2 | Primary | Low BMI / high levels of exercise; People concerned about delays in conception; High BMI; Stressful lifestyle | Encourage increase or decrease in BMI if needed; Encourage lessening of intense exercise and other stress inducing activities; provide advice per NICE CG156/1.2 | Induce ovulation - advice x 3 cost of grant | £ 36 | 60 | 60 | n/a | £ 2,160 |
| 1.2.2 | 1.1.3.1 | Primary | Do not prescribe fertility medication prior to referral to specialist | Refer to Fertility specialists | Fertility specialists to manage pathway | | | | | |
| | | | | | Primary Care total | £ 206 | | | | £ 16,560 |
| 1.2.2 | 1.3.3.2 | Fertility Clinic | Ovarian reserve testing in line with NICE CG156 Section 1.3.3.2. | | | | | | | |
| 1.2.2 | | HSC Laboratories (women) | Total antral follicle count of less than or equal to 4 for a low response and greater than 16 for a high response [AFC] | AFC (either AFC or AMH, not both) | Predictor of ovarian response/aging | £ 50 | 30 | | | £ 1,500 |
| 1.2.2 | | HSC Laboratories (women) | Anti-Müllerian hormone of less than or equal to 5.4 pmol/l for a low response and greater than or equal to 25.0 pmol/l for a high response [AMH] | AMH | Predictor of ovarian response/aging | £ 75 | 30 | | | £ 2,250 |
| 1.2.2 | | HSC Laboratories (women) | Follicle-stimulating hormone greater than 8.9 IU/l for a low response and less than 4 IU/l for a high response [FSH] | FSH | Predictor of ovulation | £ 25 | 60 | | | £ 1,500 |
| 1.2.2 | | HSC Laboratories (women) | Serum gonadotropin test for irregular menses | hCG | Determine current ovarian activity | £ 25 | 60 | | | £ 1,500 |
| 1.2.2 | 1.3.11 | HSC Laboratories (women) | Test for Rubella status | IgG | Positive result = immunity | £ 60 | 60 | | | £ 3,600 |
| 1.2.2 | 1.3.9 | HSC Laboratories (men and women) | Clinic - Hepatitis B vaccination for partners of Hep B carriers | Hep B vaccine | | £ 35 | 10 | | | £ 350 |
| 1.2.2 | 1.3.10 | HSC Laboratories (men) | Sperm washing for HIV positive men only (not Hep B) who are not compliant with HAART or their plasma viral load is >50 copies/ml. | PVL | | £ 50 | 0 | | | £ - |

| | | | | | | | | | | |
|-------|---------|---|--|---|---|---------|-----|-----|-----|-----------------|
| | 1.3 | HSC Laboratories (men) | Andrology workup (staff and consumables) | Only done in exceptional cases | | £ 200 | 5 | | | £ 1,000 |
| 1.2.2 | 1.3.8 | Surgical (women) | Investigation of suspected tubal and uterine abnormalities in line with NICE CG156 section 1.6: | | | | | | | |
| 1.2.6 | | Imaging (women) | Pelvic ultrasound x 3 | Pelvic ultrasound - gynaecological | | £ 390 | 53 | | | £ 20,670 |
| 1.2.6 | | Imaging (women) | Pelvic MRI, pre- and post-contrast | MRI Pelvic - gynaecological | | £ 163 | 13 | | | £ 2,119 |
| | | Imaging (women) | Pelvic MRA, fibroid | MRA Pelvic | | £ 200 | 3 | | | £ 600 |
| 1.2.5 | | Imaging (women) | Pituitary disorders | MRA Pituitary | | £ 200 | 2 | | | £ 400 |
| | | Imaging (women) | Gynaecologist-ordered MRI head | MRI Head with contrast | | £ 200 | 4 | | | £ 800 |
| 1.2.6 | 1.3.8.1 | Imaging (women) | Proximal tubal obstruction | Hystero-Salpinography plus tubal catheterisation (Guided Imaging) | Diagnose state of fallopian tubes | £ 500 | 20 | | | £ 10,000 |
| 1.2.6 | 1.6 | Surgical (women) | Proximal tubal obstruction / | Tubal microsurgery by laparoscopy | Deemed to be more effective | £ 2,500 | 0 | 0 | | £ - |
| 1.2.6 | 1.6.3 | Surgical (women) | Amenorrhoea | Diagnostic-only hysteroscopy (Theatre) | Investigate abnormal bleeding | £ 450 | 15 | 15 | | £ 6,750 |
| | 1.6.4 | Surgical (women) | Intrauterine adhesions / polyps or other adhesions | Operative hysteroscopy: polypectomy or adhesiolysis within uterus (Theatre) | Surgical correction of intrauterine adhesions - restores normal cycle, encouraging conception, lowers miscarriage rate. | £ 2,500 | 34 | 34 | 8 | £ 85,000 |
| | 1.7 | Surgical (women) | Leiomyoma (fibroid uterine tumours) | Myomectomy (Theatre): remove fibroids from uterus | Improve conception rate | £ 2,600 | 5 | 4 | 1 | £ 10,400 |
| | | Surgical (women) | Suspected endometriosis | Diagnostic laparoscopy | Identify endometrial issues | £ 3,000 | 28 | 24 | 4 | £ 72,000 |
| | | Surgical (women) | Endometriosis | Endometrial biopsy | Detects ovulation/infection | £ 162 | 95 | 79 | 16 | £ 12,798 |
| | | Surgical (women) | Endometriosis | Endometrial ablation | Not conducive to pregnancy | £ 2,000 | 6 | 6 | 13 | £ 12,000 |
| | | | | | | | | | | £ - |
| | | Imaging (men) | Scan to determine epididymal issues | Referral to tertiary provider | | £ 130 | 10 | 10 | | £ 1,300 |
| 1.2.3 | 1.4.1 | Medical (men) | Gonadotropin (hypogonadism) | Gonadotropin injections | No data for 2017 | £ 1,200 | | | | £ - |
| | | Diagnostic (men) | Sperm analysis | Sample | Fertility Services workup | £ 130 | 30 | 30 | | £ 3,900 |
| | | | | | Sub total Fertility Service | | | | | £250,937 |
| | | | | | | | | | | |
| | | | | Counselling per NICE guidelines | | | | | | |
| 1.2.5 | 1.5.2 | (ovulatory disorders) | WHO Group II ovulatory disorders | Clomifene (Clomid) and Cyclogest - monthly cost | Induce ovulation | £ 24 | 233 | 233 | n/a | £ 5,592 |
| 1.2.5 | | Medical mgmt (ovulatory disorders) | Polycystic ovary syndrome | Gonadotropins (Gonal-F) - monthly cost | Induce ovulation, follicle stimulation | £ 405 | 173 | 173 | n/a | £ 70,065 |
| 1.2.5 | 1.5.3 | Medical mgmt (ovulatory disorders) | Hyperprolactinaemic amenorrhoea | Dopamine agonists | Induce ovulation | | 0 | 0 | | £ - |
| | | | | | Sub total fertility drugs | | | | | £ 75,657 |
| | | | | | 2017 TOTAL spent on fertility assessments & surgical interventions to aid fertility | | | | | £367,154 |

| | | | | | | | | | |
|--------|------------------------------------|---------------------------------------|--|--------------------------------|---------|---|--|--|----------|
| 1.2.9 | Preservation of fertility (cancer) | Cryopreservation of semen | Storage at tertiary facility - annual cost | | £ 595 | 1 | | | £ 595 |
| | Preservation of fertility (cancer) | FSH | | | £ 2,000 | 1 | | | £ 2,000 |
| | Preservation of fertility (cancer) | Egg retrieval, counselling, follow up | | | £ 3,615 | 1 | | | £ 3,615 |
| | Preservation of fertility (cancer) | Oocyte retrieval | Tertiary service | | £ 2,750 | 1 | | | £ 2,750 |
| | Preservation of fertility (cancer) | Cryopreservation of oocytes | Storage at tertiary facility - annual cost | x 10 years? | £ 6,000 | 1 | | | £ 6,000 |
| | Preservation of fertility (cancer) | Frozen embryo transfer cycle | If needed later | | £ 1,520 | 1 | | | £ 1,520 |
| | | | | Subtotal per preservation case | | | | | £ 16,480 |
| 1.2.10 | fertility (other reasons) | Individual applications to IFR | One in past three years to IFR | | | | | | |
| | | | | | | | | | |

Notes regarding data in this report

1. Assuming 60 couples approach Primary Care in 2018 for investigation of infertility (58 in 2017)
2. Total cost of approx. £380,000 in 2017 for 60 couples = £6,300 per couple to reach a diagnosis of infertility, OR preparedness for natural conception.
- 2a. Laboratory costs for IUI of £14,350, incurred in 2017, are not included in the above total, since they are no longer offered under Policy G1029.
- 2b. Specialist time and outpatient time for IUI is not included in the above, since it will not be incurred in 2018.
3. Prescription of fertility drugs must be limited to Fertility specialists, and not permitted in Primary Care.
4. Estimated per case total cost for preservation of fertility for exceptional patients as defined in Policy G1029 = approximately £16,830 per couple.
5. All Guernsey patient activity is for 2017, and sourced from either DeepSee or LIMS.
6. All imaging data and surgical numbers above includes only individuals of IVF-agegroup [women 25-42, men 25-50] ordered by Gynaecologists or Urologists who do fertility assessment, and procedural numbers are not double-counted.

Fertility services

Policy G1029 sets out what is routinely funded by the Committee for Health & Social Care (CHSC) and the Committee for Employment & Social Security (CESS) and what is currently excluded from the care pathway for the investigation and treatment of infertility.

Policy G1029 is designed to be read in conjunction with document: The National Institute for Health and Care Excellence's Clinical Guidance 156: Fertility problems: assessment and treatment.

This amended version of Policy G1029 includes only minor adjustments to guidance as to who should order certain diagnostic tests within a normal fertility workup. The purpose of this is to correct inefficiencies and duplications as identified by clinical staff.

| | |
|----------------------------|--|
| Lead Professional/Author | Corporate Commissioning Policy |
| Consultation List | Professional Guidance Committee, minor corrections 2018 Clinical Reference Group |
| Version | 3 |
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Key words: Commissioning policy, health care funding, infertility service, IVF, in-vitro-fertilisation

Committee for Health and Social Care Policy

Fertility services

This is a controlled document. As a controlled document, the correct version of the document is the one available on CHSC intranet and the States of Guernsey website.

Version History

| Version Number | Date | Person responsible | Prepared by (title of author/reviewer) | Status | Reason for Issue |
|----------------|------------|---------------------------|--|---------|--|
| 1.0 | | | | | Under States, Billet d'Etat II Feb 2002 IVF is excluded from State funding of health care services |
| 2.0 | April 2017 | Director of Public Health | Public Health Advisor | Adopted | <p>This policy does not alter the States resolution.</p> <p>This policy sets out in more detail funding for fertility services and takes into account evidence based guidelines for the management of fertility. Its aim is also to clarify the confusion over what will and will not be funded to the investigation and fertility problems.</p> |
| 3.0 | Jan 2018 | Medical Director | Policy writer | Adopted | This revision does not alter the States resolution. It clarifies specific tests and procedures which should occur only by request of the secondary Fertility Service. |

Committee *for* Health & Social Care Policy

Fertility services

G1029

- 1.1 This policy applies to any patient for whom Committee *for* Health & Social Care and the Committee *for* Employment & Social Security have responsibility for funding defined elements of their healthcare.
- 1.2 The follow elements of the fertility pathway **will be funded**:

1.2.1 *Referral to MSG*

The service will see patients who meet the definitions of infertility (which includes patients who cause of infertility is unknown or patients who present particular challenged with respect to conception) as set out in NICE CG156 Section 1.2.13.

1.2.2 *Investigations of infertility to provide a definitive diagnosis and therefore enable the couple to consider management options.*

Tests which may be done in primary care prior to referral:

Blood test to measure serum progesterone to establish fertility.
Chlamydia testing.

Tests which should be done under supervision of the fertility clinic:

Ovarian reserve testing in line with NICE CG156 Section 1.3.3.2.
Blood test to measure serum gonadotrophins for women with irregular menstrual cycles.
Investigation of suspected tubal and uterine abnormalities in line with NICE CG156 Section 1.6.
Semen analysis
Sperm washing only for HIV positive men who are not compliant with HAART or the plasma viral load is 50 copies/ml or greater.
Hepatitis B vaccination for partners of people with Hepatitis B.
Testing for rubella status.

1.2.3 ***Medical management for male infertility***

All medical management should be done under the supervision of the fertility clinic.

Gonadotrophin for men with hypo-gonadotrophic hypogonadism.

1.2.5 ***Medical management of ovulatory disorders***

All medical management should be done under the supervision of the fertility clinic, and fertility drugs should not be prescribed by Primary Care

Clomifene citrate to induce ovulation.

Gonadotrophins.

Dopamine agonists for women with hyperprolactinaemia.

1.2.6 ***Surgical management for female infertility***

Tubal microsurgery, laparoscopic tubal surgery and tubal catheterisation or cannulation.

Surgical correction of intrauterine adhesions.

1.2.7 ***Surgical management of endometriosis***

Surgical correction of intrauterine adhesions.

Surgical ablation in line with NICE CG156.

1.2.8 ***Intrauterine insemination***

Unstimulated intrauterine insemination where the man is HIV positive, non-compliant with HAART or has a high viral load and where sperm washing has been recommended.

Unstimulated intrauterine insemination for couples who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm.

1.2.9 ***Preservation of fertility for patients undergoing cancer treatment***

Cryopreservation of semen and oocytes for an initial period of 10 years.

Patient's need to be informed that CHSC will not at this stage fund the use of stored gametes.

1.2.10 ***Preservation of fertility for patients for other exceptional indications***

Preservation of fertility will be considered for patient with other conditions on a case by case basis.

1.3 The follow elements of the fertility pathway **will not be funded**:

1.3.1 ***Diagnostics, tests, procedures and treatments per NICE CG156 do-not-do list:***

Post-coital testing of cervical mucus.

Ovarian volume, ovarian blood flow, inhibin B, oestradiol (E2) for the assessment of ovarian reserve.

Prolactin measurement.

Thyroid function tests in the absence of any symptoms of thyroid disease.

Endometrial biopsy in the absence of other clinical symptoms and signs.

Routine hysteroscopy as part of the initial investigation.

Additional cervical smear tests outside of the normal screening programme

Anti-oestrogens, gonadotrophins, androgens, bromocriptine or kinin-enhancing drugs for the treatment of idiopathic semen abnormalities.

Corticosteroid for the treatment of the presence of anti-sperm antibodies.

Antibiotic treatment for men with leucocytes in their semen.

Gonadotrophin-releasing hormone for women with polycystic ovary syndrome who are being treated with gonadotrophins.

Adjuvant growth hormone treatment with gonadotrophin-releasing hormone agonist and/or human menopausal gonadotrophin during ovulation induction in women with polycystic ovary syndrome who do not respond to clomifene citrate.

Pulsatile gonadotrophin-releasing hormone in women with clomifene citrate-resistant polycystic ovary syndrome.

Medical treatment of minimal and mild endometriosis diagnosed as the cause of infertility in women.

Medical treatment of moderate or severe endometriosis following surgical management.

Oral ovarian stimulation agents (such as clomifene citrate, anastrozole or letrozole) to women with unexplained infertility.

Treatments for ejaculatory failure (all currently unproven)

Treatments for epididymal blockage

1.3.2 ***Any artificial means of fertilisation***

This includes:

- 1.3.2.1 Chlamydia screening for women those undergoing IVF treatment.
- 1.3.2.2 Salpingectomy for women with hydro-salpinges before IVF treatment.
- 1.3.2.3 Intrauterine insemination including the preparation and procedure except for those indications set out in 1.2.18.
- 1.3.2.4 In-vitro fertilisation including: the assessment for suitability for IVF pre-treatment screening including testing for hepatitis BSAg, hepatitis BCore, hepatitis C, HIV, syphilis, all elements of treatment (drugs, harvest, fertilisation and transfer) and hormonal monitoring during treatment.
- 1.3.2.5 Donor insemination including procurement, preparation and procedure.
- 1.3.2.6 Intracytoplasmic sperm injection (including genetic counselling, preparation and procedure).
- 1.3.2.7 Funding of oocyte donations.

1.3.3 ***Reversal of sterilisation including semen analysis following reversal***

1.3.4 ***Surrogacy***

1.4 Private fertility treatments

- 1.4.1 All costs associated with private infertility treatment will need to be paid for by the patient or couple. This includes for example testing for infection prior to undergoing invasive procedures and all drug costs.
- 1.4.2 Shared care arrangements while undergoing fertility treatment should be between the private facility in the UK and the infertility specialists on island acting in a private capacity.
- 1.4.3 In circumstances where the UK fertility clinic recommends off label use of a treatment under a shared care arrangement, the local private clinician is at liberty to decide whether or not they wish to accept clinical responsibility for prescribing. If not all drugs will have to be prescribed and dispensed in the UK.
- 1.5 If a clinician considers exceptional circumstances might apply an application can be made for consideration through the Individual Funding Request process.

Appendix 1

Guidance for referral into secondary care specialist services

People who are concerned about delays in conception despite lifestyle and other advice from their general practitioner (usually after one year of normal unprotected sex)

People who are unable to, or would find it very difficult to, have vaginal intercourse.

A woman of reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment and investigation along with her partner.

A woman of reproductive age who is using artificial insemination to conceive (with either partner or donor sperm) should be offered further clinical assessment and investigation if she has not conceived after 6 cycles of treatment, in the absence of any known cause of infertility. Where this is using partner sperm, the referral for clinical assessment and investigation should include her partner.

For people for whom there is planned treatment which may result in infertility (such as treatment for cancer).

People who are concerned about their fertility and who are known to have chronic viral infections such as hepatitis B, hepatitis C or HIV.