



MERCK SERONO

IN ASSOCIATION WITH MERCK SERONO



Job codes: RH09-0054 & RH09-0067 Date of preparation: June 2009

This supplement has been sponsored by Merck Serono. Editorial control of this supplement has been retained by Health Service Journal apart from the foreword which was commissioned by Merck Serono



CONTENTS



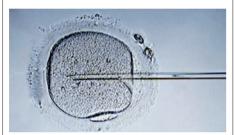
Supplement editor Daloni Carlisle Sub editor Jessica Moss Design Jennifer van Schoor

ACCESS



If you want to have a baby why should it make a difference where you live? At last the fertility treatment postcode lottery is changing Page 2

EAST OF ENGLAND



Hitting the target: NHS East of England is showing the way towards complying with NICE guidance on infertility services in full Page 5

CONFERENCE



Commissioning of fertility services is fraught with challenges but England's first conference dedicated to the subject has grasped the nettle Page 6

SINGLE EMBRYO TRANSFER



What are the pros and cons of multiple and single embryo implantation? It is certain that one solution won't fit all cases Page 8

CLARE LEWIS-JONES FOREWORD

Time to standardise NHS fertility services

'The amount and

treatment still

between PCTs'

type of NHS fertility

varies dramatically

For many infertile couples in England, the area where they live can greatly affect their chances of starting a family together. Studies estimate around one in six couples seek specialist help, but currently the amount and type of fertility treatment offered by the NHS varies dramatically in different primary care trusts. The importance of accessible IVF treatment for infertile couples should not be underestimated: it is

difficult to fully comprehend the distress and heartache that must come from knowing that treatment is possible, but unavailable in your area.

The National Infertility Awareness Campaign, led by Infertility Network UK, has been canvassing for improvements in fertility

services since 1994. It celebrated a major breakthrough in 2004 when the National Institute for Health and Clinical Excellence published a set of guidelines called Fertility: assessment and treatment for people with fertility problems. This stated that eligible couples should be offered three full IVF cycles if the woman is between 23 and 39 years of age, and intra-cytoplasmic sperm injection should be considered for those with specific male fertility problems or in whom previous IVF treatment cycles have been unsuccessful. Many people expected this guidance to be the catalyst that would end the postcode lottery for infertile couples and standardise NHS fertility services.

Five years after publication of the NICE guidance great discrepancies still exist in the level and accessibility of fertility services across the country. By 2007 around 95 per cent of PCTs were not meeting NICE guidelines. Results from a survey published in June 2009 show that the situation is improving in some areas, as in NHS East of England and in Camden primary care trust, but there are still inequities across many parts of the country.

Commissioners are crucial to moving this forward, yet they are in a difficult position. Budget constraints may be forcing them to divert funds to higher priority healthcare areas and, furthermore, the complexity of the fertility treatment could be making it difficult to bring the service up to standard cost effectively.

There is every reason, however, to feel positive about the future of NHS fertility

services, and, as these pages will demonstrate, increasing support is now available for PCTs to improve services. Case studies from fertility services that have been redesigned to meet the NICE standards show that the targets are achievable and can be accomplished cost effectively. Such

examples can now be used as a guideline for how the necessary changes can be implemented.

Tools and extra support for PCTs which need to improve their fertility services are also becoming available, such as the Commissioning Guide and Dr Scott Wilkes' Blueprint for referrals.

Infertility Network UK has also been commissioned by the Department of Health to provide advice and consultancy during these changes, using our experience to help effectively implement the necessary changes within fertility services. I am confident that,

in the coming years, infertile couples will have easier access to the high quality fertility services they should be entitled to, regardless of where they live. ● Clare Lewis-Jones is the chief executive of Infertility
Network UK.









30 July 2009 Health Service Journal supplement 1

•

ACCESS

Geographically, access to IVF cycles varies hugely, although in the past two years more regions and individual PCTs are following the lead of the best. Daloni Carlisle reports

Let's play a little game. Can you spot the difference between these two national newspaper headlines? Here is the first: "IVF: how a generation of women is being denied the chance to give birth". And the second: "Fertility treatment on the NHS is still a lottery five years after guidelines".

Give up? The answer is: three years. The first was a headline from The Independent in April 2006 and the second from The Daily Telegraph in June 2009. Both pieces covered the geographical discrepancies in the provision of NHS funded IVF. Couples are still facing a postcode lottery. This is despite the World Health Organisation defining infertility as a clinical condition with a significant impact on mental and physical wellbeing and ministerial backing for equal access. It is also in spite of National Institute for Health and Clinical Excellence guidance saying the NHS should offer three full stimulated cycles to women aged 23-39 with an identified cause for their fertility problems or who have infertility of at least three years' duration (see box, opposite).

While one primary care trust offers three cycles, its neighbour offers one.

"It's the unfairness that is so wrong," says Infertility Network UK communications manager Susan Seenan. "Why does someone in the East of England get three cycles while someone in Oxford gets one?"

Headlines, of course, are all about selling papers. The data tells a different story – one of rapid improvement over the past two years that was not reflected by *The Daily Telegraph*'s headline. The picture in 2007 was indeed pretty poor. A Department of Health survey of all PCTs revealed that only 5 per cent were offering three full cycles of IVF as recommended by NICE and 36 per cent offered only one full cycle. This means that around 95 per cent of PCTs were not meeting NICE standards. But a repeat survey published in June 2009 showed 27 per cent offering three full cycles. This shift is the result of several years' work by

'Why does someone in the East of England get three cycles while someone in Oxford gets one?'

ministers, patient groups such as Infertility Network UK, and industry to reach the people who can make a difference: PCT commissioners.

June 2009 saw not only the publication of the new survey of PCT provision, but also England's first conference for commissioners of fertility services, new model access criteria (see pages 6-7 for details on both of these) and a new commissioning aid. Work is under way on a national tariff, which is expected in two to three years.

Pivotal time

Sally Cheshire, who chairs the DH's expert group on commissioning NHS fertility provision and is a non-executive director at NHS North West, says: "This is a pivotal moment. We know we are seeing improvements, particularly in the past year."

There is still a long way to go – three quarters of PCTs are not compliant with NICE guidance.

New public health minister Gillian Merron told the conference: "Some still have nowhere to turn but to the private clinics. And that is wrong: until we change this they are, as one woman who wrote to the DH said, 'condemned to a childless life unless I pay for treatment'."

The general agreement at the conference was that the tide has turned. Ms Merron pointed out: "We expect the number of PCTs offering three full cycles to rise to one third as they review their policies in the coming year."







Ms Cheshire explains what has been going on behind the scenes since 2004 when the NICE guideline first came out. Until then the debate had been about whether the NHS should fund infertility treatment at all – it still is in some quarters.

Ms Cheshire says: "The NICE guidance of 2004 was a real breakthrough and at that time the then health secretary John Reid said he wanted PCTs to move from funding one cycle to three cycles of IVF. But there was no timescale for being fully compliant with the NICE guideline and PCTs have held back recently, arguably because it was not clear whether NICE was going to review its guidance."

Then along came Dawn Primarolo, minister for public health until the June 2009 reshuffle. She was very supportive of moves to standardise NHS fertility treatment and in late 2007 set up an expert group to advise her.

The campaigning was already in hand witness the high media profile of the IVF postcode lottery - and it was felt it was time to focus on commissioners.

Mrs Cheshire says: "The first priority was to encourage commissioners to comply with existing guidance. So the DH set up the group to look at the barriers facing them. It

was very much working with them, not against them and most members of the expert group are NHS commissioners themselves."

These barriers were neatly summarised in the group's August 2008 interim report. First, it points out that infertility is not seen as a traditional NHS service and has low priority. This may link into the second barrier: lack of commissioning expertise.

It said: "Expert commissioning skills and resources need to be developed and maintained if fertility services are to be commissioned in an equitable way to meet patients' needs. The commissioning of these services is complex and commissioners need a clear understanding and knowledge of treatments and commissioning options. At present the lack of knowledge and understanding of infertility and its treatment, as well as consistent and sustained expertise in commissioning fertility services, is a barrier in some areas."

Mrs Cheshire points out that this is quite variable in itself.

"Services are either commissioned by individual PCTs, groups of PCTs or by specialist commissioning groups," she says. "If you are a single PCT it becomes really difficult to be able to be experts about all →4

CLARIFYING NICE GUIDANCE

Fertility: assessment and treatment for people with fertility problems was published by NICE in 2004. It says eligible couples should be offered three full IVF cycles if the woman is 23-39 years of age, and intracytoplasmic sperm injection should be considered for those with specific male fertility problems or when IVF treatment cycles have been unsuccessful. This was

welcomed but the expert group on commissioning NHS infertility treatment's August 2008 interim report asked: would it be reviewed, and what is a "full cycle"?

NICE has clarified its position, saying: "Embryos not transferred during a stimulated in vitro fertilisation treatment cycle may be suitable for freezing. If two or more embryos are frozen then they should be

transferred before the next stimulated treatment cycle because this will minimise ovulation induction and egg collection, both of which carry risks for the woman and use more resources."

The full cycle of IVF is regarded as the fresh cycle plus the transfer of frozen embryos where possible.

But some PCTs are still funding only fresh cycles, the June 2009 survey shows.







3← of the complex services you commission. We have demonstrated that the deep level of knowledge needed is not there and cannot be there in all cases without expert support."

NICE was not planning a commissioning guide for fertility services so the expert group developed a commissioning aid. It is now available on the DH website and has been tested by its world class commissioning panel. It covers:

- background to infertility and its causes
- investigations and treatments, including where they take place and the current clinical pathways
- a spreadsheet to help gauge demand in a local area
- good practice in commissioning, including service specification
- best practice in procurement, including

from the independent sector where most IVF treatment takes place

- targets for managing provider performance
- planning and budgetary issues.

Ms Cheshire says: "We hope the commissioning aid will support the world class commissioning of infertility services from start to finish, from understanding the basics of what infertility is and who it affects through to policy and planning, costs and managing provider performance.

"We have tried to address all the barriers that we think there are to implementing NICE guidance. We hope it is a comprehensive effort to help commissioners overcome them."

Will it work? That is hard to say, especially in the current economic climate.

"It would be good to see all PCTs follow

the fantastic examples of NHS East of England and NHS North East and implement NICE guidance in the next 12 months," says Mrs Cheshire.

"Realistically I guess there is a caveat: it is up to PCTs to decide what money to put in to fertility services. As chair of the expert group, I would like to say implement in the next 12 months. As a strategic health authority I know the reality is that commissioners have to make choices. So the big question will be what happens to NHS funding in the longer term? It would be a shame if we did not continue to make great progress in this area."

Like many others, though, she is optimistic.

"The dominoes are lined up and they are starting to fall," she says. "This time I think we are going to see real change."

MODEL FOR IVF REFERRAL: HOW SCOTT WILKES AND COLLEAGUES DEVELOPED A BLUEPRINT

When I was a GP registrar more than a decade ago I became aware that the management of infertile couples in the NHS was not as good as it could be. While we could investigate sperm problems and ovulatory problems, we had no way of assessing tubal status and had to refer patients to secondary care to complete the initial investigations.

If hysterosalpingosonography (fallopian tube ultrasound) was available as an open access investigation to GPs, I thought, then a diagnosis could be established in primary care. Open access HSG would allow GPs to work up patients fully and refer them appropriately, whether that is to secondary care or tertiary care. It has the potential to streamline patient pathways and may cost less.

Take couples where the HSG shows blocked tubes. Secondary care not licensed by the Human Fertilisation and Embryology Authority is inappropriate for these couples, who need treatment with IVF at an HFEA licensed tertiary care fertility centre. Referral to secondary care for diagnosis resulted in longer waits and added costs for the NHS; open access HSG could reduce these.

Over the past decade I have been working with colleagues to test this hypothesis, starting with a pragmatic cluster randomised controlled trial to see whether open access HSG made a difference to the infertile couples' care pathway. This was published in May this year in the British Journal of General Practice. In summary, it showed a low uptake of open access HSG by GPs (9 per cent) but of those patients who did have this performed their pathway was shortened by an average of 10 weeks. An interview study of infertile couples, GPs and fertility specialists, also published in the journal this May, showed that open access HSG was a sensible innovation and a service that should remain in place beyond the end of the trial.

The other development has been publication of a referral blueprint.

This was developed by the independent multidisciplinary working group of Infertility Network UK with the involvement of the Royal College of Obstetricians and Gynaecologists and we hope it will serve as the model for negotiating open access HSG.

The referral form is fairly straightforward, requiring the usual demographic data and the relevant clinical record. It has space for GPs to record local NHS eligibility criteria – which helps avoid ineligible patients being referred into secondary care for HSG only to be told that they must pay privately for IVF – and some suggested routes for referral for treatment of infertile couples (see diagram).

Already I am working with a number of PCTs to implement this. It is not easy as there are many barriers, even to something apparently so simple. The following list is drawn from my experience with these PCTs:

- Lack of knowledge by commissioners about patient pathways in infertility treatment
- Resistance by some consultants in secondary care who fear that open access HSG may deskill them
- Questions about who foots the bill for open access HSG. Is it commissioned separately or in the gynaecology referral tariff?

All these are resolvable, though not overnight. The first is a question of education; the second is a question of negotiating the primary-secondary care interface. Answers to the third may be provided by the move towards elective single embryo transfer to reduce the incidence of multiple births, which may help to offset the cost of open access HSG in primary care.

If all GPs with an informal interest in infertility used this referral blueprint, I believe it would save infertile couples weeks and months of delay and the NHS a significant amount of money.

Dr Scott Wilkes is honorary clinical senior lecturer in primary care at the Institute of Health and Society, Newcastle University and a practising GP.







lacksquare

EAST OF ENGLAND

Cycle of life

Patchy policies across NHS East of England have been replaced with a region wide promise to offer up to three IVF treatment cycles. Kaye McIntosh explains

Women in the East of England are being offered up to three IVF treatment cycles, under a policy drawn up by the first region to come close to implementing the National Institute for Health and Clinical Excellence guidance on infertility services in full.

"East of England has set the standard," says Infertility Network UK chief executive Clare Lewis-Jones. "I hope others will follow."

The region was keen to tackle "an ever increasing number of complaints, queries and appeals", says Trevor Myers, East of England specialised commissioning group director.

Other factors included the Department of Health's drive for primary care trust NICE compliance, and contracts between Hertfordshire and Essex PCTs and providers coming up for retender.

Policies across the region were patchy, says Mr Myers, with some PCTs permitting only one cycle, others two or three, and patients facing a range of eligibility criteria, some outside those recommended by NICE.

Now patients will be able to receive up to six embryo transfers at one of five fertility service providers. Providers should first use a fresh embryo, then any frozen embryos until there is only one left, before moving on to a new IVF cycle.

Mr Myers expects the overall cost of providing three cycles of IVF to those who meet the criteria to be up to an additional £12m-£13m.

"We felt that was a development that needed to happen and a cost we would have to bear," he says.

In a region of 5.5 million people, he calls this "quite good value", adding: "There will always be a cost associated with NICE guidance but, divided by 14 PCTs, on average we are talking less than £1m per PCT."

The process was led by a



project steering board, including an acute clinician, a GP, commissioners, a public health consultant, finance director and members of the specialised commissioning group, and Ms Lewis-Jones. The specialised commissioning group held workshops for commissioners and secondary care clinicians to gain support and input into the service specification, taking

'Providing three cycles needed to happen and was a cost we would have to bear'

account of advice from Infertility Network UK.

The recommendation to provide three cycles was approved by a group of PCT directors of commissioning, before going to the specialised group's board, made up of the 14 PCT chief executives in the region. The board's decision to

approve the proposal was unanimous.

Carolyn Young, associate director of the group, says: "There was a willingness to move to NICE compliance; the debate was at what speed that would be done."

The decision to go straight to three cycles rather than move in steps, first offering two and then three, was contentious, Ms Young says. But the argument that two steps would add complexity and delay won out.

And, Ms Young says, by going straight to three cycles the region benefits from economies of scale: "We got a better price from clinics as we were commissioning on such a large scale, across the region."

The tendering process was "technically difficult", says Mr Myers, as the specialised group had to work with the NHS competition and contestability guidance, while taking account of EU legislation and English case law, but reached "an outcome that put providers through a rigorous process and provides more choice to patients than ever before".

Five clinics have been appointed to provide infertility services, which have to meet strict quality requirements:

- Barts and The London Centre for Reproductive Medicine
- Bourn Hall Clinic, Cambridge
- IVF Hammersmith
- Leicester Fertility Centre
- Oxford Fertility Unit.

A fertility forum, including primary and secondary care clinicians, will meet quarterly to discuss activity and progress. The region also plans to set up a patient satisfaction survey.

Ms Young says a key factor in getting the policy in place was ensuring all stakeholders were involved and on board, including patient representatives: "That was incredibly important and persuasive for PCTs."

It also ensured the service specification focused on patient expectations, such as clinic opening times and the availability of counselling, rather than solely clinical issues.

Ms Young adds: "We have been working on this for 18 months so it is very satisfying to see it up and running." ●





COMMISSIONING CONFERENCE

Is wishing to start a family a medical need or a lifestyle choice? This is just one of the questions facing commissioners of infertility services. Daloni Carlisle reports on a conference where some of the issues were thrashed out

WHOSE PROBLEMIS ITANYWAY?

To say the commissioning of fertility services is fraught with difficulties would be an understatement. Here, in no particular order of priority or complexity, are some of the challenges that were outlined at England's first conference for fertility commissioners – with some of the help now available to meet them.

Providing IVF on the NHS is a political hot potato that is rarely out of the news. Human Fertilisation and Embryology Authority chair Lisa Jardine argued that much of this public debate is rooted in the notion that wishing to start a family is a lifestyle issue, whereas her view is that infertility is a medical condition and should be treated like any other.

This posed difficulties for commissioners who are battling with hard choices about where to spend limited resources and may also face this argument, but, paradoxically, they were in the position to ensure fertility services become well embedded in NHS provision.

She said: "The way that infertility treatment is commissioned has an enormous impact on the perception of the population at large about whether or not people are entitled to feel that they should have access to treatment that will affect their lives cataclysmically."

It is an area where the technology and the clinical evidence base are both moving fast. According to National Institute for Health and Clinical Excellence medical associate director Tim Stokes, a 2008 literature search in preparation for next year's planned review of the NICE guideline on fertility showed it may require "major changes to many recommendations, including revisions to key priorities for implementation".

Dr Stokes said NICE would start reviewing the guideline in April 2010, aiming for publication of the new version between December 2011 and April 2012, depending on the amount of revision required.

Competing services

The next challenge concerns tendering, service specification, contestability and contracts. Some of this derives from the plurality of fertility service providers, with multiple health service and independent providers competing for business.

This means commissioners must be both transparent in their tendering and robust in their specifications, said Neil Wilson, director of NA Wilson Associates consultancy, which provided support for the East of England specialist commissioning group as it developed new NICE compliant services during 2008-09 (see page 5).

He said: "You have to be ready for a challenge at any stage of the commissioning process because there are significant commercial interests at stake here."

He added: "One of the lessons we learned was that you have to eliminate conflicts of interest. We had wanted to bring in clinicians from both the private and NHS providers, but they had conflicts of interest because they were potential bidders. We had to let them go for the tendering process and make very sure that the clinical adviser who was evaluating the bids had no conflict of interest."

The next challenge is costing. There is no national tariff for IVF, meaning primary care trust commissioners face very difficult costing issues that can get bound up in access issues.

Take the issue of donated gametes, raised by one delegate who wanted to know whether PCTs should fund IVF cycles using them. Sally Nelson, public health consultant and medical adviser to NHS South Central's specialist commissioning group, explained the core issue.

The problem is that private clinics often reduce the charges for a private patient who is prepared to donate an egg, Dr Nelson said, and then, to compensate, charge the NHS an inflated rate to treat the woman receiving the donated egg.

One solution, she suggested, was to fund this only when the couple sourced their own egg.

She said commissioners had to "develop policies on how far you are prepared to go and debate with providers about the price at which they will offer egg



'PCTS approach this in different ways and patients find it hard to comprehend'

donation and whether it is something you can prioritise."

Work is now underway on a tariff that would help solve this and other issues, including the wide variation of the cost of IVF between providers. Already, the NHS Information Centre has drawn up 20 new health resource groups that will be considered for approval in September 2009. Project manager Peter Taylor outlined a timeline to the conference that would see a draft tariff ready for testing by April 2011 and national roll out in 2012.

Access criteria are another thorny issue. The Department of Health's 2009 survey of PCT provision has uncovered a wide variation in the groups of patients PCTs are prepared to fund. While some reject smokers, for example, others offer help to smokers to quit by the time they are undergoing treatment. Some refuse to fund IVF for couples where either partner has a child, regardless of whether that child is living with them or not. The DH wants these standardised and has now given its backing to a new set of access criteria developed by





















Top, left to right, Lisa Jardine, Gillian Merron and Peter Taylor Middle, left to right, Clare Lewis-Jones, Neil Wilson, Sally Nelson and Tim Stokes; below: conference delegates share the animated discussion



Infertility Network UK and

launched at the conference.

Merron said: "Across the

Public health minister Gillian

country, we know different PCTs

approach this in different ways.

And patients, including my

constituency, find it hard to

comprehend why we can get

something in one area and not

"The standardised access

work towards removing these

criteria at the moment was

social judgement and this was

not acceptable, said Infertility

criteria will help commissioners

Much of what informed PCTs'

Network UK chief executive Clare Lewis-Jones.

"The standardised access criteria we have developed are based on principles of clinical effectiveness, cost effectiveness and needs assessment," she said. "In reviewing their criteria, commissioners should carefully consider the origin of the criteria they use and the extent to which they are justified."

The first criterion recommended by the network concerns the definition of infertility.

"We are not in the business of rewriting NICE guidance," said Ms Lewis-Jones. "We endorse the definition by NICE and the British Fertility Society that it should be defined as failure to conceive after regular unprotected sexual intercourse for two years in the absence of known reproductive pathology."

PCTs should take into account previous treatment with IVF, again in line with NICE, and should not fund IVF for people who have been sterilised.

The criteria also endorse NICE's guidance on female age range (23 to 39 years at the time of treatment) and NICE's recommendation that IVF is most clinically effective in women with a body mass index of 19-30 and in non-smokers.

But couples who fall outside these smoking and weight criteria should be helped towards them, not simply rejected, said Ms Lewis-Jones: "Some patients cannot even get a referral to an infertility specialist to get specialist advice at the moment. They cannot get through the door."

Heartbreak for couples

Perhaps the most contentious issue is previous children. The access criteria say: "PCTs should move towards a position where funding is available for those who do not have a living child, including couples where one partner is childless."

This would end the heartbreak for couples where the father has a child with a former partner and who are therefore denied access to NHS funded IVF.

It goes on to say: "As investment in fertility services increases, funding may be available for IVF where both partners have a child/children from a previous relationship but not from the current relationship."

It is a recommendation that is a long way from current

provision, as shown in the June 2009 DH survey, and a position that Mrs Lewis-Jones defended saying it was based on needs assessment: "If a couple is childless they are deserving of treatment."

No one is arguing that getting to the DH's desired situation, where access to NHS funded IVF treatment does not depend on where you live, is easy, but at last some of the help that commissioners so badly need is now available.

The last word should go to Ms Merron, who thanked NHS commissioners for the hard work it has taken to get this far.

"You're the ones who have to take the difficult decisions," she said. "You're the ones who are assessing local needs and balancing local priorities. And you're the ones who put in place the services we all use. And I'm looking forward very much to working with you all and learning from you all."

Find out more

Department of Health primary care trust survey – provision of IVF in England 2008

→www.dh.gov.uk/en/ Publicationsandstatistics/ Publications

Infertility Network UK standardising access criteria to NHS fertility treatment

→www.infertilitynetworkuk.com









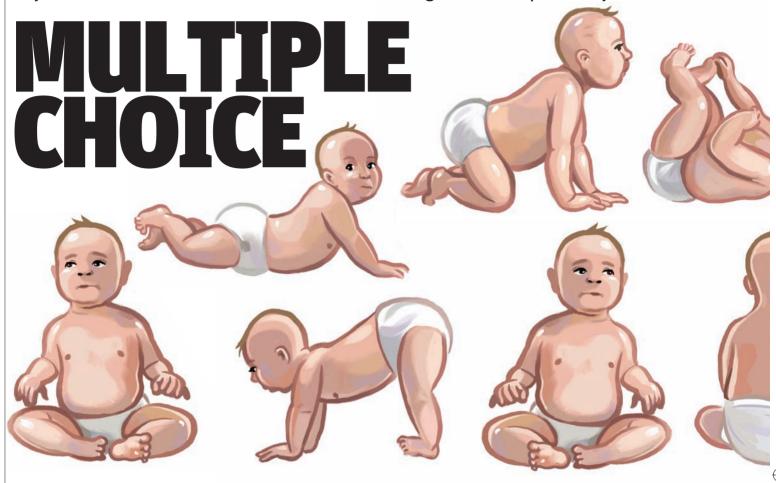
in another.

inequities."



SINGLE EMBRYO TRANSFER

Kaye McIntosh looks at the risks and rewards of single and multiple embryo transfer



"You can fully understand that for a woman having IVF treatment the idea that twins would be an ideal outcome – an instant family," says director of the Multiple Births Foundation Jane Denton. Yet twins or triplets carry real health risks for mothers and babies, as well as significantly increasing the costs to the NHS."

A quarter of IVF births are multiples, compared with one in 80 conceived naturally. Fertility clinics often implant two embryos to improve the chances of a successful outcome, or even three. But multiple pregnancy is linked to serious problems.

Between 40 and 60 per cent of IVF neonates are transferred to intensive care, compared with around 20 per cent of single IVF infants. Of those, 8 per cent need assisted ventilation, compared with 1.5 per cent of singletons. A few will have ongoing health problems, including disabilities such as cerebral palsy.

The risks are outlined in the 2006 report *One At A Time – better outcomes from fertility treatment*, which brought together experts including members from the Human Fertilisation and Embryology

Authority, British Fertility Society, Infertility Network UK and Multiple Births Foundation.

Risks to mothers

Around 20 per cent of women carrying IVF twins suffer from high blood pressure, compared with only 1-5 per cent of those with singletons. The risk of pre-eclampsia is up to 30 per cent for twin pregnancies compared with 2-10 per cent for those with just one baby.

The authority is working with the other experts involved in the *One At A Time* campaign to bring down multiple birth rates from IVF.

The aim is to encourage fertility clinics to transfer just one embryo at a time in suitable patients, known as single embryo transfer.

The policy also aims to tackle the massive burden avoidable multiple births place on the NHS. A twin IVF pregnancy costs the health service nearly three times as much as one with a single baby – more than £9,000 compared with £3,000, excluding the cost of infertility treatment itself. That shoots up for triplets, to nearly 10 times as much as a single IVF baby.

The 2006 study that uncovered these figures, *The Costs to the NHS of Multiple Births after IVF Treatment in the UK* looked only at pregnancy and neonatal care, not ongoing needs. It reviewed all published data on the topic and is cited by the authority and other experts as the most reliable cost data.

Now the authority has told all fertility clinics to draw up a documented multiple births



minimisation strategy. It has asked centres to bring down their multiple birth rates to the national average of 24 per cent this year, as the first stage of a three-year plan. Clinics with rates below the average already should try to reduce them further. The "aspiration" is to reach 10 per cent within three years, says authority policy manager Jessica Watkin.

"We have taken the novel step of deciding on an outcomes based approach rather than being prescriptive," she says. The authority needs to analyse the figures from this year on, before setting any firm targets, she adds.

"We are not hell bent on bringing multiple birth rates down to any figure in any particular timescale. It is a complicated issue and we are acting in partnership with patients and professionals."

Yet those who hold the NHS purse strings are not generally aware of the economic and health impact of IVF twins or triplets, Ms Denton says. The authority's multiple births stakeholder group has had "a very poor response from commissioners", with few keen to attend meetings.

Ms Watkin says the authority wrote to NHS commissioners in February to explain its guidelines.

"We recognise that this is a complex issue but we would urge them that it is vital for the success of this policy that their commissioning strategies are in line with the minimising multiple births strategy. They should look at the multiple birth rates of centres and factor those into their commissioning decisions."













'It is a cost effective use of resources to use frozen embryos and to avoid multiple births'



Clinics with very high rates of multiple births may not be suitable for NHS contracts, she adds.

Talk to clinicians

Tony Rutherford, chair of the British Fertility Society, representing gynaecologists and other health professionals, says: "I would dearly hope NHS commissioners are aware of the HFEA and BFS guidance on minimising multiple births. It is very important that they talk to their clinicians."

But, he warns, it is vital that commissioners understand that single embryo transfer is not appropriate for every patient.

"You have to leave the clinician and the scientist to select which would be the best patients."

Ms Watkin agrees: "Single embryo transfer is not a one size fits all solution to multiple

Forcing it on a woman in her 40s with a history of failed IVF attempts would not be fair, she says, as it would reduce the chances of success.

Instead, she argues that primary care trusts funding IVF should have "consistent

commissioning policies that have regard to our multiple births strategy".

Dr Rutherford says: "HFEA data shows 87 per cent of multiple pregnancies are in women on their first cycle of IVF aged under 37 and that is a good population for elective single embryo transfer."

Clare Lewis-Jones, chief executive of Infertility Network UK, agrees: "ESET is the right move but NHS funding needs to come alongside it to be fair to patients."

It is vital NHS commissioners follow National Institute for Health and Clinical Excellence guidance, defining one IVF cycle as including implantation of both fresh and frozen embryos, Ms Watkin adds.

A woman should first receive a fresh embryo, then if that attempt is unsuccessful, use any frozen embryos, before starting a further round of fertility drugs to stimulate her ovaries to produce more eggs.

Ms Lewis-Jones says: "At the moment there is a slight drop in the overall conception rates on the first fresh cycle [of elective single embryo transfer]. We need to use frozen embryos to bring that figure back up. It is a cost effective use of resources to include frozen embryos and avoid multiple births."

Yet the latest Department of Health figures show that in 2008, 59 out of 152 PCTs were not funding any frozen embryo transfer, although a handful said they would move to funding both fresh and frozen cycles in the 2009-10 financial year.

Ms Lewis-Jones says: "Just funding fresh cycles is not what the NICE guidelines said and it is not acceptable with the move to single embryo transfer – patients will not accept it; it is almost a token gesture. The chances of one fresh cycle with

one embryo working depend on a number of factors but it is not an effective service for infertility." Ms Lewis-Jones goes on

Ms Lewis-Jones goes on to say: "Some PCTs are just funding one fresh cycle, not any frozen embryos.

> "This is not cost effective, clinically effective or fair to patients."

It is largely down to lack of knowledge, she adds: "For three years we have been working with PCTs to identify the barriers to implementation of the NICE guidelines and share good practice. We have found a lot of them don't honestly know a full cycle is both fresh and frozen embryos."

Dr Rutherford points to positive developments in NHS Yorkshire and the Humber as an encouraging sign. The region has consulted the HFEA, involved the BFS and taken local clinicians' views on board while drawing up its infertility treatment strategy. But, Dr Rutherford adds, competing priorities for NHS funding will always be an issue.

Ms Lewis-Jones agrees it all comes down to economics.

"We need a national tariff for fertility treatment so that the NHS is charged the same across the board for fresh and frozen embryo implantation by clinics. That is what the HFEA's Expert Group on Multiple Births After IVF recommended."

While ministers have taken this on board, Ms Lewis-Jones expects the complex process of designing a tariff to take two to three years – so it is vital that PCTs follow the authority policy on minimising multiple births, together with fully implementing the NICE guidelines, in the interim.

Dr Rutherford says: "Our argument is that preventing multiple births by using ESET allows the NHS to reduce its overall costs and is safer for mothers and babies."

FIND OUT MORE

The Costs to the NHS of Multiple Births after IVF Treatment in the UK. William Ledger et al, British Journal of Obstetrics and Gynaecology, 2006

→www.bjog.org



