

THE SCOTTISH EXECUTIVE

**REPORT OF THE
REVIEW OF INFERTILITY SERVICES
IN SCOTLAND**

MARCH 2007

1. Executive Summary

The Scottish Executive has reviewed the access criteria for NHS-funded level III assisted conception treatment (ACT). Level III ACT includes in-vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI) and is provided at four tertiary centres in Aberdeen, Dundee, Edinburgh and Glasgow.

Recommendations for access to these treatments were developed by the Expert Advisory Group on Infertility Services in Scotland (EAGISS) in 2000 and NHS Boards were asked to implement these recommendations within existing resources. In 2004 the National Institute for Health and Clinical Excellence (NICE) published guidelines for the treatment of infertility in England and Wales which differed in some respects from the EAGISS recommendations. Over 2003-4 modifications to the EAGISS recommendations were proposed, based on new evidence on treatment effectiveness. Table I shows the EAGISS recommendations and NICE guideline for the areas covered in this review.

Implementation of the EAGISS recommendations has been variable in Scotland, with 9 NHS Boards being compliant by 2005, while a small number of Boards use criteria more similar to the NICE guideline. Waiting times for treatment vary significantly across Scotland; in 2005 waiting times for ACT were between 2 and 60 months.

This review was undertaken to seek views on making changes to the criteria for access for level III ACT in order to obtain maximum effectiveness and equity of treatment. The review took the form of a consultation involving service providers and other stakeholders. Respondee were asked to consider options for clinical and non-clinical access criteria for level III ACT, including the EAGISS recommendations, NICE guideline and, in some cases alternatives. The review also requested respoonees' comments on the implications of possible changes to access criteria for treatment waiting times and resource requirements. A total of nine questions were included in the consultation.

Twenty-six responses were received, including 15 NHS Boards, 5 individuals and 6 organisations, including patient support networks and professional (medical) associations.

The responses to the questions on access criteria are summarised in Table I below. Responses to questions about waiting times and resources are summarised below.

- Any widening of access criteria for level III ACT will increase waiting times, though this impact is likely to be variable across Scotland.
- Substantial resources would be required for most NHS Boards to reduce waiting times below 12 months.
- Respoonees were almost universally opposed to prioritising the provision of one IVF cycle in order to reduce waiting times for treatment.
- Respoonees wanted a consistent policy on waiting list management across Scotland.
- Respoonees did not clearly favour or oppose regional commissioning of level III ACT.

Table 1. EAGISS Recommendations, NICE guidelines and consultation responses on criteria for access to level III Assisted Conception Treatment.

	Age of female	Number of cycles	Timing of subsequent cycles, if first unsuccessful	Other Clinical criteria	Non-clinical criteria
EAGISS recommendations (2000)	Female should not have reached her 38 th birthday at the time of treatment	Maximum of 3 embryo transfers, including 2 fresh cycles and one transfer of frozen embryos. If no frozen embryos, one additional fresh cycle.	Once treatment started, couples allowed to undergo subsequent treatments within a time-frame of their choosing.	Infertility with an appropriate diagnosed cause of any duration <i>or</i> unexplained infertility of at least 3 years duration.	Neither partner previously sterilised <i>and</i> no child living in the home.
NICE guidelines (2004)	Female is 23-39 years old, i.e. should not have reached her 40 th birthday at the time of treatment	Maximum of 3 complete fresh cycles, if two or more frozen embryos available, these should be transferred before next fresh treatment cycle.	No guidance given by NICE, <i>but</i> Secretary of State indicated that one IVF cycle should be funded initially, with more cycles being funded incrementally.	Appropriate diagnosed cause of infertility <i>or</i> unexplained infertility of at least 3 years duration <i>or</i> absolute indication for IVF in a woman younger than 23 years of age.	No non-clinical criteria identified, <i>but</i> Secretary for State stated that priority should be given to the childless.
Response to consultation	Clear majority preference – female should not have reached her 40 th birthday at the time of treatment	Majority preference – up to five cycles including no more than three fresh cycles.	Clear majority preference for EAGISS recommendations – couples should not return to waiting list after each cycle.	Not included in consultation.	No clear preference for a specific changes to criteria, though 70% of respondees favoured some relaxation of non-clinical criteria.

2. NEXT STEPS

The Scottish Executive is publishing an interim response to this review, providing revised recommendations for clinical criteria for access to level III ACT, which are based on clinical evidence, take into account the responses to this consultation and aim to improve access to infertility treatment across Scotland.

Additional research and modelling will be undertaken to evaluate the impact and resource implications of changes to waiting list management. The Scottish Executive will use this additional evidence to draft recommendations on an approach to waiting list management for level III ACT that take into account the responses to this consultation and aim to increase the equity of access to ACT across Scotland.

The Scottish Executive expect to consult with service providers and other stakeholders in developing recommendations on waiting list management, which will be published in the summer of 2007.

3. INTRODUCTION

Infertility is recognised as a health need in Scotland and NHS funded assisted conception treatment has been widely available for many years. However there has been concern over inconsistency in accessing NHS funded fertility treatment, or ‘postcode prescribing’. In recognition of this problem the Expert Advisory Group on Infertility Services in Scotland (EAGISS) was set up in 1988 by the Clinical Resource and Audit Group (CRAG) under the auspices of the Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH).

EAGISS reviewed the evidence base and clinical management of infertility services in Scotland and developed a National Service Framework which aimed to provide equity of access and improve the overall quality and effectiveness of service. The report was published on 11 February 2000, as *Evidence and Equity: Review of criteria for NHS-funded assisted conception treatment*. The Scottish Executive asked NHS Boards and NHS Trusts to work towards full implementation of the Group’s recommendations within existing resources.

The most significant recommendation of the EAGISS group was the establishment of common national criteria for accessing NHS funded level III treatments, i.e. those that require a licence from the Human Fertilisation and Embryology Authority. These treatments, which include In-Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI) are delivered in four tertiary centres in Aberdeen, Dundee, Glasgow and Edinburgh.

Since publication of the Framework, a review of implementation in 2002 showed limited implementation of the national criteria by NHS Boards. A conference convened in January 2003 by the Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH) recommended alterations to the national criteria. These recommendations were based on new evidence on treatment effectiveness which indicated that widening of the national criteria was appropriate. In addition the National Institute for Health and Clinical Excellence (NICE) published guidelines for the treatment of infertility in England and Wales in February 2004 which were similar, though not identical to the revised Scottish criteria.

In 2004 The Scottish Executive Health Department asked NHS Quality Improvement Scotland (NHS QIS) to consider the NICE guidelines and SPCERH recommendations, NHS QIS proposed revision of the EAGISS criteria to bring them more closely into line with the NICE guidelines. SEHD agreed to write to NHS Boards, informing them of these revised recommendations and to request comments, as part of a public consultation exercise. Comments would also be sought from other interest groups.

This document analyses the responses to that consultation exercise. The document does not consider the evidence base for the different recommendations, which is contained in other reports referenced throughout. The consultation and this report cover criteria that relate only to **Level III assisted conception services** delivered within the tertiary centres in Glasgow, Dundee, Edinburgh and Aberdeen.

4. BACKGROUND TO CONSULTATION

In February 2000, the Scottish Executive Health Department published *Evidence and Equity*, the report of an Expert Advisory Group on Infertility Services in Scotland (EAGISS), along with NHSMEL2000 (06) which advised Health Boards and Trusts to use the recommendations in the report as the basis for planning their infertility services. The recommendations referred to the age of the female being treated, the number of cycles of treatment that should be funded and included clinical and social criteria for establishing eligibility for NHS-funded treatment. In summary these were:

Age: The upper female age limit should be 38 years. i.e. the female should not have reached her 38th birthday at the time of treatment.

Number of cycles: Couples should be offered a total of 3 embryo transfers, of which 2 could be fresh cycles, plus one transfer of stored, frozen embryos. Stored frozen embryos should be transferred before further fresh cycles of treatment are offered. In couples where there were no frozen embryos, three fresh cycles could be offered.

Timing of subsequent cycles: Once accepted onto an assisted conception treatment (ACT) programme, couples should be allowed to undergo successive cycles within a time frame of their own choosing – they should not return to the beginning of the waiting list following an unsuccessful cycle.

Non-clinical criteria: Neither partner previously sterilised, and no child living in the home.

Clinical criteria: Infertility with an appropriate diagnosed cause of any duration *or* unexplained infertility of at least 3 years duration.

In March 2003 the Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH) convened a consensus conference to consider new evidence relating to eligibility for assisted conception. The conference made recommendations on age, number of cycles and criteria for eligibility for NHS-funded treatment:

Age: Women aged less than 41 years at time of treatment (i.e. female must be before her 41st birthday at the time of treatment)¹.

Number of cycles: Up to three complete fresh cycles, any available frozen embryos to be transferred before a new fresh cycle. Total number of embryo transfers (fresh and frozen) not to exceed five. Less than five previous embryo transfer attempts funded from any source.

Timing of subsequent cycles: Once accepted onto an ACT programme couples should be permitted to undergo successive treatments within a time frame of their own choosing. They should not return to the end of a waiting list following an unsuccessful cycle.

Non-clinical criteria: No child living with the couple in their home *and* neither partner previously sterilised.

¹ This recommendation was based on unpublished data indicating that success rates for assisted conception for women aged 41 were approximately 10%. EAGISS recommendations were that treatments should not be offered where success rates were below 10%.

Clinical criteria: Infertility with an appropriate diagnosed cause of any duration, *or* unexplained infertility of at least three years duration.

Other recommendations: The eligibility criteria should be re-applied for each treatment cycle, in particular once the woman reaches the age of 41 she would no longer be eligible for treatment.

These recommendations were reported to the Chief Medical Officer and to NICE, who were consulting on infertility treatment guidelines at this time.

NICE produced infertility treatment guidelines which were launched in February 2004. NICE did not make any recommendations for the use of social or other non-clinical criteria in the provision of NHS-funded treatment. The NICE guidelines identify good practice points for eligibility for level III assisted conception treatment, as follows:

Age: The woman is 23 to 39 years old (i.e. female is before her 40th birthday).

Number of cycles: Treatment should consist of a maximum of 3 complete fresh treatment cycles, if two or more frozen embryos are available, these should be transferred before the next fresh treatment cycle.

Clinical criteria: There is an appropriate diagnosed cause of infertility *or* unexplained infertility of at least 3 years duration, *or* there is an absolute indication for IVF in a woman younger than 23 years of age.

Non-clinical criteria: No non-clinical criteria were identified in the NICE guidelines.

The Secretary of State for the Department of Health at this time responded to the NICE guidelines, as outlined below.

Age: Agreed with the NICE guideline for age of female partner

Numbers of cycles: Indicated that one IVF cycle should be funded initially, with more being funded incrementally.

Social Criteria: Stated that in implementing the NICE guideline, priority should be given to those who are childless.

Clinical Criteria: Restated the need for proof of infertility, i.e. failure to conceive after regular unprotected sexual intercourse of 2 years, in the absence of reproductive pathology. This effectively excluded single sex couples and single women from receiving assisted conception treatments funded by the NHS.

In May 2004 the Scottish Executive Health Department asked NHS QIS to review the evidence used to inform the NICE guidelines against the evidence used to inform the recommendations made at the SPERCH consensus conference (March 2003). SEHD agreed to recommend changing the EAGISS criteria to fall in line with the NICE guidelines for age of female and number of cycles of treatment, as follows:

Age: Age of female to be increased from 38 (up to 38th birthday) to 39 (up to 40th birthday at the time of treatment).

Number of cycles: An increase in the number of embryo transfers from 3 (including 2 fresh and 1 frozen) to 5 (including 3 fresh and 2 frozen).

In September 2005 the Scottish Executive Health Department wrote to NHS Board Chief Executives advising them of the more recent recommendations updating the EAGISS criteria to widen eligibility for access to IVF services. The letter highlighted the potential implications for resources and waiting lists and requested responses to a series of questions in a consultation paper. The aim of the consultation was to obtain views on how and whether to implement the revised criteria, in order to give maximum effectiveness of treatment and ensure equity of access to IVF services.

The consultation paper was also made available electronically to enable wider participation by stakeholders in the process.

5. CURRENT POSITION

A number of revisions, as detailed above have been proposed to the EAGISS criteria recommended to NHS Boards in 2000. However these revisions have not been formally produced as new guidance to NHS Boards in Scotland. There is no requirement on the NHS in Scotland (or England and Wales) to implement NICE guidelines. NHS Boards therefore have had some discretion over whether they seek to adopt the EAGISS guidelines or aim for the NICE guidelines in funding ACT.

Implementation of the EAGISS guidelines in Scotland

No timescale was given for adopting the EAGISS criteria; however progress has been monitored by the Executive on several occasions. By 2005 the following 10 Boards were compliant with the access criteria laid out in the EAGISS report of 2000:

Ayrshire and Arran	Lanarkshire
Borders	Lothian
Dumfries & Galloway	Orkney
Fife	Shetland
Grampian	Western Isles

Of the remaining Boards the majority are either only slightly different from the EAGISS criteria, or have wider access criteria.

NHS Board	Areas where access criteria are exceeded
Argyll & Clyde	Female upper age limit for treatment is 40 but only 2 NHS funded embryo transfers
Forth Valley	Minimum 4 years of unexplained infertility
Greater Glasgow	Female upper age limit for treatment is 40 and 2 year minimum duration of unexplained infertility
Highland	Female upper age limit for treatment is 39
Tayside	Female upper age limit for treatment is 40 but 4 year minimum duration of unexplained infertility

The adoption of the criteria has had an inconsistent impact on waiting lists. The majority of waiting lists have decreased since 2001, however some have increased and the difference between the shortest and longest remains considerable. Table 2 sets out these changes.

Table 2, Average waiting times for IVF 1988-2005.

NHS Board	Ave Waiting Time for IVF in Aug 1998 (pre EAGISS)	Ave Waiting Time for IVF in 2001	Ave Waiting Time for IVF in 2004	Ave Waiting Time for IVF in April 2005
Argyll and Clyde*	30	27	7	7
Ayrshire and Arran	24	24	6	8
Borders	60	48	3	3
Dumfries and Galloway	30	24	19	19
Fife	24	24	24	24
Forth Valley	-	4	9	10
Grampian	24	24	48	60
Greater Glasgow	36	18	8	7
Highland	24	12	18	6
Lanarkshire	24	-	-	11
Lothian	36	9	12	24
Orkney	9	0	0	8
Shetland	-	0	6	2
Tayside	33	24	24	24
Western Isles	-	-	-	-

Waiting Times quoted are in months

* Figures refer to pre-dissolution of Argyll and Clyde NHS Board

- **NUMBER EITHER TO SMALL TO ASSESS / NOT RECORDED / NOT AVAILABLE.**

Implementation of the NICE guidelines in England

Monitoring of the impact of the NICE guideline in England has indicated that the recommendations are not being widely implemented. There is evidence that although the total number of cycles of ACT has increased, the majority of Primary Care Trusts (PCTs) are funding 1 fresh cycle of treatment only.

A survey of providers of assisted conception treatments in England was published in 2006². The review showed that despite publication of the NICE guidelines, inequality of access to ACT remains, in large part due to variable application of non-clinical criteria for eligibility. In particular, a range of social definitions of infertility are used as selection criteria, including neither partner having previous children, couples with no children at home and previous sterilisation of neither partner. Some service providers would only provide treatment for females in stable heterosexual relationships; others required proven infertility in the case of same sex couples.

The NICE guidelines recommend provision of three fresh cycles of treatment, followed by replacement of up to two frozen embryos from those cycles. However no centres surveyed

² Kennedy et al, [Human Fertility](#); September 2006; Volume 9 No. 3 Pages 181 - 189

reported that they were being commissioned by PCTs for three fresh cycles, while 90% were being commissioned for one fresh cycle only, with half of these following up with replacement of frozen embryos arising from the fresh cycle.

The NICE guidelines recommend females should be eligible for treatment between the ages of 23 and 39. Seventy four percent of centres surveyed followed this recommendation.

Kennedy *et al* conclude by recommending that explicit planning will be required to fully implement the NICE guidelines and provide consistency in the criteria used for NHS-funded assisted conception treatment.

6. THE CONSULTATION

The consultation document 'Review of infertility services in Scotland' sought views on revisions to the national criteria for access to Level III infertility treatments, changes to service commissioning and the likely impact of any changes on waiting times and resource requirements.

Objectives of the consultation

1. To identify criteria that give improved access and availability of assisted conception services to those who need it.
2. To reduce variation in waiting times for treatment across Scotland and aim for couples to obtain their first treatment within 12 months of joining a waiting list.
3. To establish how the revised criteria should be implemented to ensure maximum effectiveness and equity of treatment.

The Consultation Process

The consultation document was issued on the 9 September 2005 and comments were invited from Chief Executives NHS Boards, Child Health Commissioners, Directors of Public Health, Medical Directors, and a range of health and other organisations and interested parties. The closing date for all responses was 8th December 2005

To enable a wider audience to participate, the document was also published electronically on the Scottish Executive's web site:

<http://www.scotland.gov.uk/Publications/2005/09/infertility-consultation/contents>.

The consultation document contained three questions, for which options were offered. Respondents were able to submit additional comments or alternative views on these questions. The document also invited responses to an additional six questions of which three were open questions inviting text responses and three were closed questions to which a yes or no response could be given, with or without additional comments.

We are grateful to all who took the time to respond to the consultation paper.

Consultation responses.

Twenty six responses were received. Respondeees included fifteen NHS Boards, 5 individuals, and 6 organisations. The 6 organisations included two medical organisations, two infertility support groups and two groups with a specific remit in infertility. A full list of respondeees is given in Annex A.

Analysis of responses

Responses to the questions were categorised and are shown graphically or in tables where clear answers to the questions were given. A number of respondeees made text responses in addition to, or in place of a direct answer to the questions. Examples of these responses are given below the tables. These have been selected to give an overview of the range of responses received, but not all comments are given and those given are not all given in full.

All responses, including textual responses have been considered and have been taken into account in the summary of the findings reported in each section.

6.1. *Should we change the clinical criteria?*

(a) Status Quo: Upper female age limit of 38 and up to 3 cycles of treatment or

(b) Consistent with NICE: Increase female upper age limit of 40 and increase number of cycles to 5 with a maximum of 3 fresh cycles.

EAGISS guidelines (status quo):

Age: The upper female age limit should be 38 years. i.e. the female should be before her 38th birthday at the time of treatment

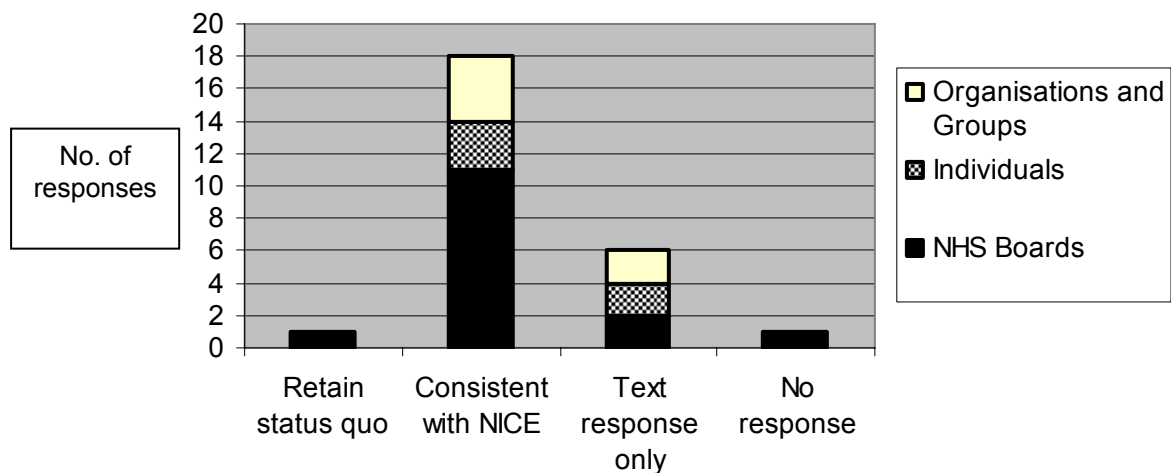
Number of cycles: Couples should be offered a total of 3 embryo transfers, of which 2 could be fresh cycles, plus one transfer of stored, frozen embryos. In couples where there are no frozen embryos, three fresh cycles can be offered.

NICE guidelines:

Age: Female between 29 and 39 years of age inclusive (i.e. up to 40th birthday).

Number of cycles: Maximum number of cycles – 3 involving fresh embryos, with a further two cycles using frozen embryos available from previous treatments.

Figure 1: Should the clinical criteria be changed (Retain status quo or consistent with NICE)



Selected text responses

- Cycles should not be undertaken after the age of 40.
- Unclear whether age limit applies to age of referral or actual age at the date of intervention.
- Age limit should be increased to between 41-45 years as couples now wait to start a family later on in life due to their careers.
- It should be made clear at what stage the upper age limit is to be applied. The current system can take several years to identify a fertility problem, by which time the upper age limit has been reached.
- Support the increase in female age from 38 to 40, however favour funding only 3 cycles of treatment with fresh embryos.
- Support NICE criteria, but once accepted onto waiting list, patients should be allowed to complete treatment even if they reach the upper age limit.
- Once female passes her 40th birthday, if frozen embryos still available, treatment with these embryos should be funded.
- Support recommendations of SPICERH consensus group: female should be added to waiting list for ACT up to 40th birthday, stimulated treatment should be completed by 41st birthday, treatment with any frozen embryos can be continued beyond this age. Total number of cycles funded should be 3, including fresh and frozen.
- Three fresh cycles should be funded, each to include subsequent transfer of any frozen embryos.

Summary

Figure 1 shows that all fourteen boards responded to this question and twelve were in favour of recommendations consistent with NICE guidelines. Two boards preferred to retain the status quo, one of these commenting that this was due to resource constraints. Seven of eleven other respondents who answered this question also favoured extending treatment provision to be consistent with the NICE guidelines, while two proposed slight variations to the NICE guidelines.

Support for the age limit within the NICE guideline was more consistent than support for the numbers of treatment cycles that should be funded.

6.2. After failed treatment, how should subsequent treatments be administered?

(a) Status Quo: Once accepted onto programme couples should be permitted to undergo successive cycles within a timeframe of their own choosing.

or

(b) Effective and Equitable: First embryo transfer has highest chance of success³, therefore to ensure effectiveness and equity couples should return to end of waiting list after first cycle.

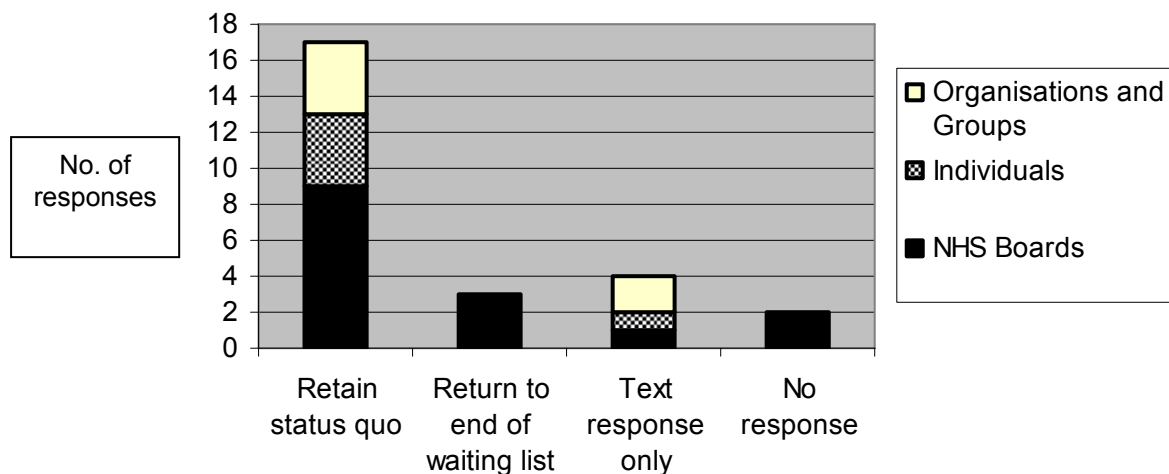
EAGISS guidelines:

Once accepted onto an ACT programme, couples should be allowed to undergo successive cycles within a time frame of their own choosing – i.e. they should not have to return to the beginning of the waiting list following an unsuccessful cycle.

NICE guidelines:

The NICE guidelines do not clearly address this question. In practice most PCTs in England appear to be taking an approach similar to the second of the options above – i.e. the provision of one cycle to as many couples as possible, in preference to three fresh cycles to couples that commence treatment.

Figure 2. How should subsequent treatments be administered (status quo or return to end of waiting list)



Selected text responses

- If couples did not return to the end of the waiting list between treatments, this would have a substantial impact on waiting list length or resources required to maintain list at current level.

³ A number of respondents did not agree with the statement that the “first embryo transfer is the one most likely to succeed.”

- Returning couples to the waiting list after one cycle of treatment would continue to consume NHS resources, in that they continue to need clinical, emotional and counselling support.
- Couples should undergo successive cycles within a reasonable timescale agreed between themselves and the clinicians providing the treatment.
- Couples should not return to the bottom of the waiting list between treatments. Maximum time between cycles should be standard across Scotland and not more than 9 months.

Summary

Figure 2 shows that a total of 24 responses were received. 13 NHS Boards responded, nine Boards preferred to retain the status quo, where couples undergo successive cycles of treatment according to a timeframe of their choosing. Three Boards wished to change to an approach where couples returned to the waiting list after each unsuccessful treatment.

Eleven responses from organisations and individuals were received to this question. The responses received did not support the second option of returning couples to the waiting list after unsuccessful treatments. Eight of these clearly preferred to retain the status quo; the other three suggested a standardised timescale.

6.3. Should we change the social criteria?

(a) Status Quo: No previous sterilisation and no other children in the home.

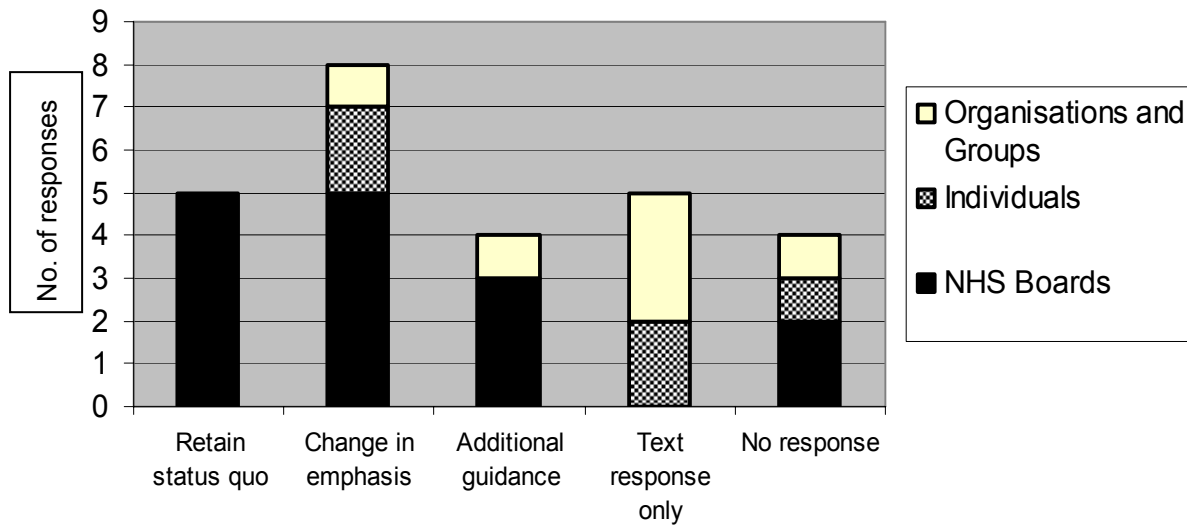
(b) Change in Emphasis 1: No previous sterilisation and priority to be given to those couples with no other children living within the home.

(c) Additional Guidance: No previous sterilisation and the couple should have no previous children as a couple, although one or both of the couple may have children with other partners.

EAGISS guidelines: Neither partner previously sterilised, and no child living in the home.

NICE guidelines: Did not include social criteria. However Minister of State for Health at the time indicated that “*priority should be given to those who are childless*”...

Figure 3. Should the social criteria be changed (retain status quo/ change in emphasis/ additional guidance)?



Selected text responses

- If people have a medical need for infertility treatments, these should be provided based on clinical rather than social criteria.
- Facing secondary infertility is actually more heartbreaking than not being able to conceive children at all.
- Treatment should be provided where the couple do not have any children although one/both may have had children with other partners, including children who are adopted.
- Further work is required to identify the impact of widening the access criteria in this way.
- Any changes beyond the status quo would have significant implications in terms of funding and waiting lists
- No previous sterilisation should continue to be a criterion.
- The status quo does not treat men and women with children from a previous relationship equitably at the moment. The additional guidance would be ideal but there are resource implications associated with managing a low priority list.
- Access should not be based on any social criteria whatsoever, however priority should be given to couples with no children.

Summary

Table 4 shows that twelve NHS Boards and four other respondents (two individuals and two organisations) answered this question with the options offered. Five respondents preferred to retain the current non-clinical criteria which restrict funded treatment to couples with no children in the home. Eight respondents preferred some relaxation of these criteria to allow funding of treatment for couples with other children in the home at lower priority. Four

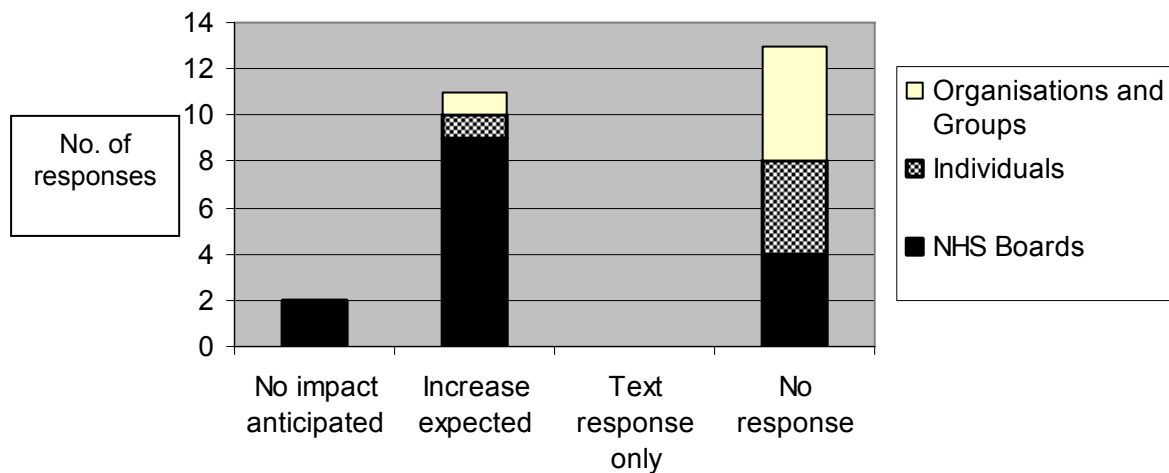
respondees preferred relaxation of the current criteria so that funding of treatment was restricted to couples who had no previous children as a couple, though one of these preferred funding of treatment for couples with children to be possible at lower priority.

Five respondees answered this question with alternative suggestions; four of these indicated that they did not support the use of non-clinical criteria in determining eligibility for NHS-funded ACT.

Respondents were asked 6 further questions, some of which were targeted primarily at NHS Boards, however where responses were received from individuals and organisations these have been shown.

6.4. What impact would widening the access criteria have to your waiting times for treatment?

Figure 4. Impact of widening criteria on waiting times (No impact anticipated, increase expected).



Selected text responses

- Will also reduce inequality whereby ability to pay determines whether couples receive treatment.
- Waiting list already unacceptably high, will deteriorate further.
- No impact on cost or effect of service provision on waiting list anticipated provided increase in age limit for female to before 40th birthday refers to age at time of treatment.
- Incremental approach preferred to introduction of changes.
- Significant impact expected if extend access to couples with no children as a couple.

Summary

Figure 4 shows that eleven NHS Boards responded to this question, with nine reporting that widening the access criteria would have a significant impact on waiting times. The other two NHS Boards either have few patients or already implement criteria very close to those proposed. The two additional responses anticipated increased waiting times as a result of widening access criteria.

6. 5. What impact would the proposed changes have to the level of funding required to maintain or reduce the waiting time to less than 12 months?

Table 3. What impact would proposed changes have to level of funding required to maintain or reduce waiting time to less than 12 months (Funding required / no funding required)? Table shows NHS Board responses only.

(£££ - substantial/considerable levels, amount not specified, £ - additional funding required, amount not specified, current waiting times in months are given where provided in responses, B1-B15 are individual NHS Boards – codes provided in annex A)

	B 1	B 2	B 3	B4	B 5	B6	B 7	B 8	B9	B 10	B11	B 12	B 13	B 14	B15
Funding required			££ £	££ £	£	>350 k	■	>60 0k	££ £		£££				£££
No funding required	■									■				■	
Current waiting time (m)	< 12	1 2	36	60		72				6	16			< 12	
No response												■	■		

Selected text responses

- There is a major problem in dealing with the backlog of couples. A 12 month waiting time target seems unreasonable when other NHS treatments must be provided in a much shorter time.
- Current resources support treatment for only half of eligible patients.
- Cost of reducing current waiting list to 12 months >£350k, any widening of eligibility criteria will increase this further.

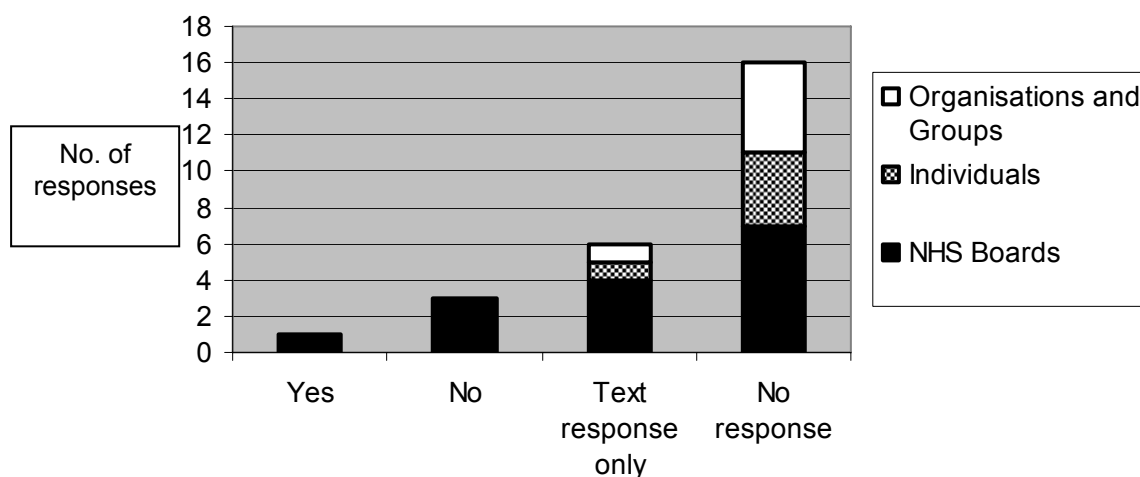
- Central funding required given other local funding priorities and that proposed changes are not evidence based.
- Real waiting times are up to 6 years in some NHS Boards – substantial funding is required to reduce to 12 months even with existing criteria.
- Costs for additional funding required for change in age limit extrapolated to Scotland estimated at approx £7.9M
- Additional costs of funding ACT according the NICE guidelines for age and cycle numbers estimated at £51M for Scotland – data from All Party Parliamentary Group on Infertility (2004).

Summary

There were eleven responses to this question, from nine NHS Boards and two organisations. Nine respondees stated that the proposed changes would require significantly increased or additional funding. A number of Boards identified substantial resource implications for reducing current waiting lists to 12 months with no extension of access to treatment - estimates of £266⁴-600k were provided for three different Boards. Three boards stated that no additional funding would be required because current waiting lists were already below the target time proposed.

6.6. *Would the proposal to return couples to the end of the waiting lists after their first cycle ensure acceptable waiting times within current resources?*

Figure 5: Would returning couples to the end of the waiting lists ensure acceptable waiting times (yes / no)?



Selected text responses

- Might shorten waiting times, but unacceptable.
- Backlog of patients would mean patients would pass age eligibility criterion.
- Would probably ensure acceptable waiting times, however would be clinically inappropriate.
- Do not support this approach to managing waiting lists.
- Prefer to retain status quo and not return couples to end of waiting lists.
- Particularly not for older women.

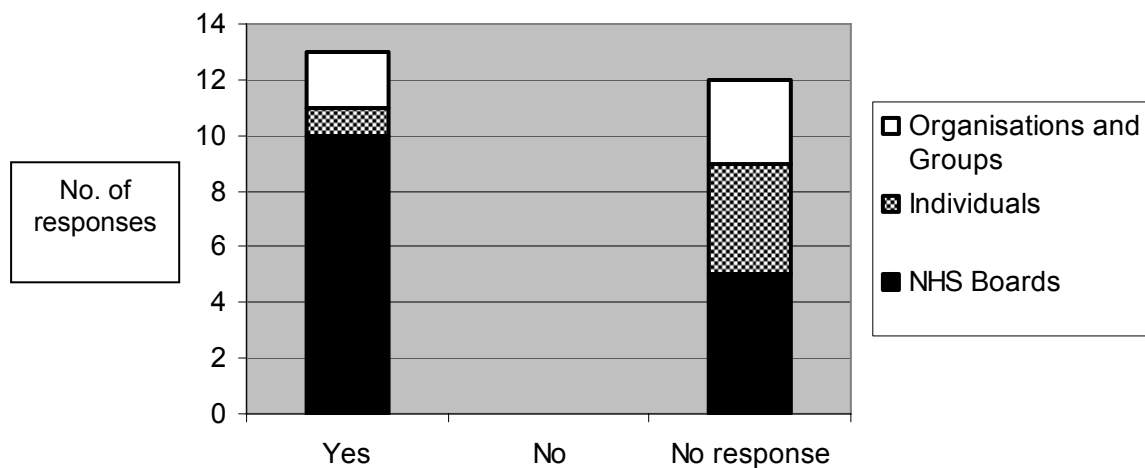
⁴ Figure supplied for one NHS Board in a response from an organisation, so not shown in table.

Summary

Figure 5 shows that nine responses were received to this question. One respondent agreed that returning couples to the end of the waiting list after an unsuccessful treatment might reduce waiting lists to 12 months or less. However no respondents believed that this was an acceptable approach. Three respondents stated that waiting lists would not be reduced to acceptable levels by this approach.

6.7. *Do you agree that the policy on whether couples return to the end of the waiting list after failed treatment must be consistent across Scotland?*

Figure 6: Agreement with policy on returning couples to the end of the waiting list after failed treatment must be consistent across Scotland (yes – agree /no- do not agree)



Additional comments

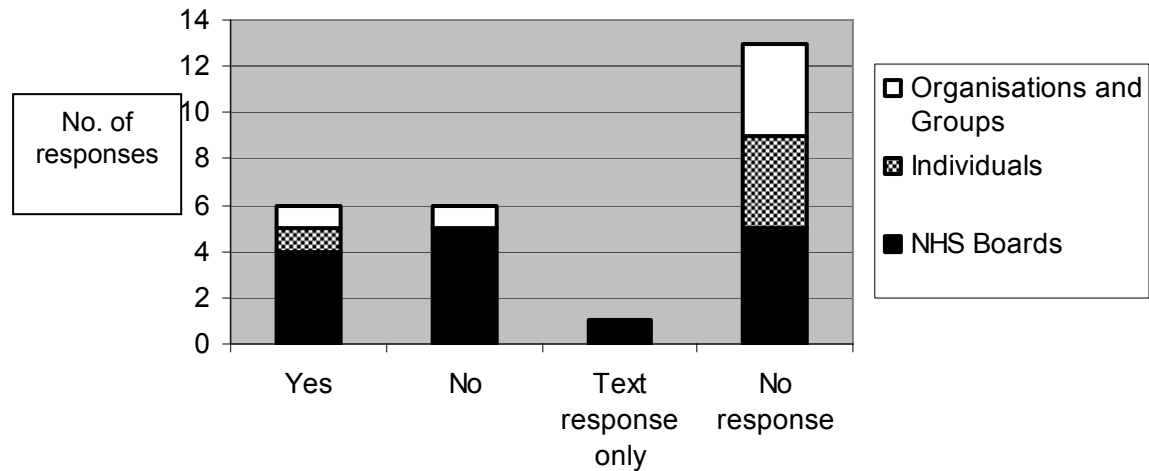
- Policy should be consistent, but do not agree that couples should return to beginning of waiting list.
- Yes, but patients in NHS Boards with long waiting lists would be disadvantaged.

Summary

Figure 6 shows that 13 responses were received to this question. All responses agreed that the policy on whether couples are returned to the waiting list after unsuccessful treatment should be consistent across Scotland. However eight respondents stated that they did not agree with returning couples to the beginning of waiting lists (see also responses to question 6.2 and 6.6).

6.8. Should level III services be commissioned regionally?

Figure 7 Should level III services be commissioned regionally?



Additional comments

- Advantages of regional commissioning unclear, patients should have access to local centre to avoid stress caused by travel.
- NHS Boards should continue to have flexibility to commission services with a particular treatment centre.
- Content with current arrangements and working relationships for local commissioning.
- Should consider regional and national commissioning.
- Only if improving cost and quality.
- Would mean a longer wait for local couples.
- Patients should have the option to be referred outside their Region.

Summary

Figure 7 shows that twelve responses were received to this question. Six responses agreed with regional commissioning of infertility treatments, with a further response agreeing with this proposal providing cost and quality improved as a result. Six respondents did not agree with regional commissioning, because they were content with their current local arrangements, or anticipated some reduction in service as a result.

6.9. *What else would assist you to offer all first treatments within 12 months of joining a waiting list?*

Summary

Ten responses were received to this question, eight from NHS Boards, one from an individual and one from an organisation. Seven of the responses stated that increased resources or funding would be required. One response stated that widening of access criteria would make existing problems more severe. One response stated that capacity issues might constrain the ability of the service to maintain waiting lists at acceptable levels.

6.10. Other comments received on related issues not directly raised in the consultation.

A number of views on related issues were expressed by more than one respondent, though they were not specifically requested in the questions. These are summarised below.

- Some respondents expressed a wish for further widening of treatment criteria. Also the need to clarify funding for prescribing drugs by primary care practitioners.
- Eight respondents stated that assisted conception treatments should be covered by waiting times directives similar to other treatments.
- Many respondents expressed a preference for phased introduction of new criteria.
- A number of NHS Boards expressed a need for clearer guidance regarding where the provision of ACT sits amongst other national priorities and local needs.
- A small number of NHS Boards expressed the view that ACT should not be a high priority compared to other clinical needs and no additional resources should be provided for these treatments.

7. CONCLUSIONS

The objectives of the consultation were:

1. To identify criteria that give improved access and availability of assisted conception services to those who need it.
2. To reduce variation in waiting times for treatment across Scotland and aim for couples to obtain their first treatment within 12 months of joining a waiting list.
3. To establish how the revised criteria should be implemented to ensure maximum effectiveness and equity of treatment.

The consultation responses have provided feedback from stakeholders on options for widening access criteria and managing waiting times. Some responses also addressed implementation of revised criteria.

Access Criteria and Availability of Service.

The consultation requested responses to options for changing the access criteria for level III ACT, which took account of recent guidelines and relevant evidence produced by NICE.

- A majority of respondents believe that the criteria for access to ACT services should be changed by increasing the upper age limit for access to ACT from the 38th birthday (EAGISS recommendation) to the 40th birthday (NICE guideline) at the time of treatment.
- A majority of respondents believe that the criteria for access to ACT services should be changed by increasing the number of cycles of treatment provided from a maximum of three, including two fresh cycles (EAGISS recommendation) to a maximum of five, including three fresh cycles (NICE guideline).
- There was no clear preference for a specific change to non-clinical criteria for access to ACT services, though 70% of respondents favoured some relaxation of the EAGISS criteria, which state that neither partner should be previously sterilised and there should be no child living in the home.

Waiting Times

Consultees were asked a number of questions about waiting times and waiting list management.

- Almost all respondents were opposed to prioritising the provision of one IVF cycle and then returning patients to the beginning of waiting lists for subsequent treatments. Respondees favoured the provision of subsequent cycles of treatment to a timetable agreed between the consultant and patient.
- Respondees favoured a consistent policy on waiting list management across Scotland. Eight respondents recommended that ACT should be subject to waiting time targets, though the consultation did not ask for comments on waiting time targets.
- Respondees did not clearly favour or oppose regional commissioning of level III ACT.
- Respondees anticipated that any widening of access criteria for level III ACT would increase waiting times, though not all service providers believed that the impact would be significant.
- Most NHS Boards stated that substantial resources would be required to bring waiting times below 12 months.

Implementation

Consultees provided some feedback on how any revised criteria or changes to waiting list management should be implemented –

- Any changes should be introduced using a phased process.

8. NEXT STEPS

The Scottish Executive is publishing an interim response to this review, providing revised recommendations for clinical criteria for access to level III ACT, which are based on clinical evidence, take into account the responses to this consultation and aim to improve access to infertility treatment across Scotland.

Additional research and modelling will be undertaken to evaluate the impact and resource implications of changes to waiting list management. The Scottish Executive will use this evidence to draft recommendations on an approach to waiting list management for level III ACT that take into account the responses to this consultation and aim to increase the equity of access to ACT across Scotland.

The Scottish Executive expects to consult with service providers and other stakeholders in developing the recommendations on waiting list management, which will be published in the summer of 2007.

ANNEX A

Respondees

Named Individuals

Mr B Dundas
Dr S Irvine
Ms A Gill

Anonymous Individuals
Two respondees

NHS Boards (with codes used in Table

B1 NHS Greater Glasgow Health Board
B2 NHS Lanarkshire
B3 NHS Lothian
B4 NHS Grampian
B5 NHS Argyll and Clyde
B6 NHS Tayside
B7 NHS Ayrshire and Arran
B8 NHS Fife
B9 NHS Forth Valley
B10 NHS Highland
B11 NHS Dumfries and Galloway
B12 NHS Borders
B13 NHS Western Isles
B14 NHS Shetland
B15 NHS Orkney

Organisations and Groups

British Medical Association
Ayrshire Infertility Support Group
Scottish parliament short life working group on fertility services
Scottish Committee of the Royal College of Obstetricians and Gynaecologists
National Infertility Awareness Campaign
Infertility Network UK