Gamete Storage Referral Policy
### Policy Title:
Gamete Storage Referral Policy

### Supersedes:

### Description of Amendment(s):

### This policy will impact on:
Patients of ND CCG Membership Practices

### Financial Implications:
No financial implications

### Policy Area:
All CCG Community

### Version No:
V1

### Issued By:
Joint Clinical Commissioning Policy Advisory Group

### Author:

### Effective Date:
October 2015

### Review Date:
October 2017

## APPROVAL RECORD

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## Revision Changes

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This policy relates to the preservation of gametes (oocytes and semen) and embryos, in post-pubertal patients, in advance of chemotherapy or radiotherapy treatment for cancer or conditions requiring male urological or female gynaecological surgery that carries a high risk of infertility.

This policy was developed following a review of the NICE Clinical Guideline for Fertility, published in February 2013, NICE Quality Standards for Fertility Problems and takes account of the Equality Act 2010, including age discrimination legislation. The policy includes criteria which are outside of the recommendations laid out within the associated NICE Clinical Guidelines. CCG Governing Bodies considered these recommendations in the context of their budget allocation for assisted reproduction services and the associated opportunity costs.

Adverse effects associated with a number of medical treatments can impact on fertility, either by direct injury or via systemically administered agents. In some cases the individual’s fertility will return after the treatment is completed but in other cases fertility never returns, or is severely impaired. Technological advances mean that cryopreservation of semen, oocytes, embryos and ovarian/testicular tissue offers opportunities to preserve fertility prior to the start of treatment.

In line with the recommendation by the NICE Fertility Guideline, access to cryopreservation and storage associated with treatment induced infertility has been considered separately to assisted reproduction services and the general fertility pathway.

Background:

Cryopreservation is a technique that freezes an individual’s eggs or sperm for use in future fertility treatment. Cryopreservation of sperm is a well-established technique used to maintain an individual’s fertility. Cryopreservation of eggs is a newer technology, though has been widely used in relation to cancer treatment for a number of years.

Policy:

Gamete cryopreservation will be commissioned in individuals undergoing medical or surgical treatment who may be at risk of permanent infertility as a result of their treatment. Gamete cryopreservation will not be commissioned for social reasons, or if gametes are being frozen for use by individuals other than the patient receiving treatment.

It should be noted that the policy does not address NHS funding for the future use of frozen gametes. Provision of gamete freezing and storage under the terms of this policy is made without prejudice to the future determination of funding of any subsequent fertility treatment.

The following are outside the scope of this policy:
• Cryopreservation of gametes and embryos in pre-pubertal patients.
• Cryopreservation of gametes and embryos and sperm requested for social reasons.

Criteria for commissioning

Patients eligible for NHS-funded gamete cryopreservation should be about to commence treatment that is thought to cause permanent infertility as a result of their treatment. Conditions considered appropriate for gamete cryopreservation are:

• Malignancies requiring chemotherapy
• Malignancies requiring total body irradiation or radiotherapy that may affect an individual's reproductive organs
• Conditions requiring male urological or female gynaecological surgery
• The impact of the treatment on the patient’s fertility has been discussed between the patient and the treating clinician.
• The patient is able to make an informed choice and consent to undertake gamete harvesting and cryopreservation.
• The patient is aware that funding for gamete harvesting and cryopreservation of material does not guarantee future funding of assisted conception or fertility treatment.
• The patient has no living children. This includes a child adopted by the patient. Continued storage will not be funded if the patient subsequently adopts a child or achieves a pregnancy leading to a live birth.
• Females of reproductive age up to 42 years old (stimulation treatment to take place prior to individual’s 43rd birthday)
• Males of reproductive age up to 55 years old (sperm retrieval to take place prior to individual’s 56th birthday)
• Registered with a GP in Derbyshire
• Individuals who have previously been sterilised will not be eligible for cryopreservation
• Written consent to treatment and gamete storage is required

Women, who are preparing for medical treatment for cancer that is likely to make them infertile, should only be offered oocyte cryopreservation if they meet all of the following criteria:

• They are well enough to undergo ovarian stimulation and egg collection; and
• there is sufficient time available to harvest eggs before the start of their cancer treatment

Women who are undergoing gynaecological surgery should only be offered oocyte cryopreservation if, following surgery, pregnancy would still be viable.
Approval of cryopreservation does not guarantee future funding of assisted conception or fertility treatment. Local fertility policies and criteria for eligibility in place in the commissioning area in which the patient is living at the time of application will apply.

Cryopreservation Services Funded

Oocyte, embryo and sperm cryopreservation will be funded for eligible patients.

Embryo storage using donor sperm is not routinely commissioned.

Male patients must have a sperm test one year after treatment, if sperm analysis is within the normal range continued storage will not be funded.

Sperm will be stored for an initial period of 5 years, automatic renewal for a further years is authorised providing the patient continues to meet all eligibility criteria.

Oocytes and embryos will be stored for an initial period of 5 years, automatic renewal for a further 5 years or up until the patient’s 42nd birthday, whichever is soonest, is authorised for patients who continue to meet all other eligibility criteria.

Storage of sperm beyond 10 years is not normally funded.

Patients who have undergone NHS funded cryopreservation but no longer meet eligibility criteria may choose to self-fund continued cryopreservation of stored material.
Surrogacy Policy
**Policy Title:** Surrogacy Policy

**Supersedes:**

**Description of Amendment(s):**

**This policy will impact on:** Patients of ND CCG Membership Practices

**Financial Implications:**

**Policy Area:** All CCG Community

**Version No:** V1

**Issued By:** Derbyshire Joint Clinical Commissioning Policy Advisory Group

**Author:**

**Effective Date:**

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Commissioning Policy
Surrogacy

1. Definitions

**Surrogacy** is the practice whereby one woman (the surrogate mother) carries a child for another person (the commissioning couple) as a result of an agreement prior to conception that the child should be handed over to the commissioning couple after birth.

**Traditional (straight) surrogacy** refers to situations where the surrogate uses her own egg fertilised with the intended father’s sperm. This is usually done by artificial insemination.

**Gestational (Host IVF) surrogacy** refers to situations where the surrogate carries the intended parent’s genetic child conceived through IVF.

**An individual funding request (IFR)** is a request received from a provider or a patient with explicit support from a clinician which seeks funding for a single identified patient for a specific treatment.

**Exceptional clinical circumstances** refers to a patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by a patient within the normal population of patients with the same medical condition at the same stage of progression as the patient.

2. The policy

2.1 This policy applies to any patient for whom the Clinical Commissioning Group CCG is the Responsible Commissioner.

2.2 The (CCG) will not provide routine funding for the medical treatment required to give effect to a surrogacy arrangement because: (a) this treatment is not considered by the CCG to be a priority for NHS investment, (b) the CCG is unlikely to be in a position to be able to reach an assessment as to whether the parties have concluded a lawful surrogacy arrangement, and (c) the CCG is concerned that the funding of such treatment raises substantial risks that NHS bodies and doctors providing care connected to surrogacy arrangements would be exposed to unknown medico-legal risks. IVF treatment will not be provided as part of surrogacy arrangements.

2.3 Please refer to the CCGs funding arrangements regarding egg storage for a woman whose will become infertile as a result of medical treatment.

2.4 For privately arranged surrogacy the NHS will continue to provide normal maternity care to the surrogate mother.

2.5 The CCG is prepared to consider providing funding for individual patients who are able to demonstrate exceptional clinical circumstances. As an extension to the normal policy the CCG will be prepared to consider funding to support
commissioning couple who have exceptional clinical circumstances as well as those of the surrogate mother to whom the treatment will be given. Any such applications will be considered by the CCG under its Individual Funding Request policy.

3. Key principles supporting this policy

3.1 The CCG will not commission any form of fertility treatment to those in surrogacy arrangements (ie the use of a third party to bear a child for another couple). This is due to the numerous legal and ethical issues involved. For this reason NHS treatment is not available.

3. Local documents which have a direct bearing on this policy

- In February 2013 NICE issued Clinical Guideline 156 (CG156), Fertility: assessment and treatment for people with fertility problems. Surrogacy was not included within the scope of CG156.


4. Documents which have informed this policy


The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009, http://www.npc.co.uk/policy/resources/handbook_complete.pdf


The Human Fertilisation and Embryology Authority, Surrogacy http://www.hfea.gov.uk/60.html

http://www.surrogacyuk.org/whatissurrogacyc.html

Appendix 1 – Background Information

The Legal Position

Surrogacy is legal in the UK but the Surrogacy Arrangements Act 1985 makes commercial surrogacy illegal.

The mother

The legal parentage remains with the mother carrying the child – regardless of whether the child is genetically related or not. If the host mother, therefore, wishes to keep the child she has been carrying, it is her right to do so.

The father

If the surrogate is married, in virtually all cases the sperm donor rules have the effect of making the surrogate husband the legal father with full parental responsibility. The surrogate’s husband’s name is therefore recorded on the birth certificate as the father, regardless of the fact he has no biological connection with the children and regardless of whether or not he attends the birth registration. Further steps have to be taken for genetic father to gain parental rights. In the past the commissioning couple had to apply for formal adoption but this process has been simplified providing certain conditions are met.

If the surrogate is not married (or her husband genuinely does not consent – signing a letter to say he does not consent is not enough) then the situation is slightly different. The intended father is, provided that he is the biological father, then the legal father at birth and his name can be recorded on the birth certificate, though only if he attends the birth registration in person together with the surrogate.

It is significant for the intended father to be named on the birth certificate in these circumstances, as this gives him ‘parental responsibility’ (‘all the rights and duties of a parent’) as well as legal parenthood. If, rarely, for any reason he cannot be named on the birth certificate, he can acquire parental responsibility afterwards either by signing an agreement with the surrogate mother or by applying to court for a parental order.

If the intended father is able to acquire parental responsibility, then he can in turn give parental responsibility to the intended mother (on the slightly strange premise that she, as his spouse, is the child’s legal step-parent). The surrogate and both intended parents simply need to sign a parental responsibility agreement after the birth is registered to do this.

An intended mother who has parental responsibility in these circumstances has legal authority to act as a parent (so she can make decisions and sign forms etc), but she does not become the legal mother. This has various implications e.g. the child has no automatic right of inheritance from her.

Her rights are also held in addition to those of the surrogate mother, who remains the legal mother with all the rights and responsibilities this entails.

Parental orders

A parental order is the means by which both intended parents acquire full legal parenthood, and extinguish all the rights and responsibilities of the surrogate and her
husband. After a parental order is granted, the intended parents are issued with a new birth certificate recording their details as the legal parents.

Though in certain situations intended parents can acquire parental responsibility without getting a parental order, it is still important to apply for a parental order as this is the only way of:

1. giving the intended mother full parenthood status (rather than just step parent parental responsibility), and

2. extinguishing the rights and responsibilities of the surrogate.

In cases involving married surrogates, the intended parents will usually have no recognition as legal parents until a parental order is granted. In situations where this causes problems (e.g. over giving consent to immunisations), it is possible to apply to the court for an interim order (a residence order) giving the intended parents parental responsibility.

Before embarking on a surrogacy arrangement it is therefore very important to ensure that you will qualify for a parental order and that you understand how the rules work. If you are in any doubt whatsoever about your eligibility, you should seek specialist legal advice. There are alternative ways of securing parenthood after surrogacy using adoption law if a parental order is not available, but the rules are complex and you risk committing a criminal offence if things are not organised properly at the outset.

The conditions for getting a parental order are:

1. The application must be made within six months of the birth (the court has no discretion to extend this time limit).

2. Both intended parents must be over 18.

3. The intended parents must be married to each other at the time of the application (civil partnership does not currently qualify, though the Human Fertilisation and Embryology Bill 2008 currently going through Parliament will change this, allowing applications from unmarried and same sex couples as well as married couples).

4. At least one intended parent must be domiciled in a part of the UK (please note that domicile is not to do with where you are living, but your origins – if you or your parents have foreign roots, you should seek legal advice on your status).

5. At least one of the intended parents is the child’s biological parent (the court may request a DNA test to prove this).

6. The child is living with the intended parents at the time of the application.

7. The surrogate has not been paid anything apart from ‘reasonable expenses’ (this is often a difficult question and great care is needed. The court does have the ability to authorise additional payments, but this power has only once been exercised).

8. The surrogate fully and freely consents (and her consent can only validly be given after 6 weeks).

9. The surrogate’s husband (if she has one) fully and freely consents.
The Department of Health’s position

The Department of Health does not have an official position on surrogacy.

The Government undertook a review of surrogacy in 1997. The resultant report recommended:

1. Payments to surrogate mothers should only cover genuine expenses associated with the pregnancy.

2. Agencies involved in surrogacy should be registered with the relevant UK Health Department and operate in accordance with the code of practice which should be drawn up by the Department of Health.

3. The Surrogacy Arrangements Act 1985 and section 30 of the HF&E Act 1990 should be repealed and replaced by a new surrogacy act.

None of these recommendations have as yet been implemented.

The Human Fertilisation and Embryology Authority

The Human Fertilisation and Embryology Authority have agreed to its use.

The medical profession’s position

The BMA has endorsed its use as an acceptable treatment but only as an option of last resort. Guidelines for clinical practice have been issued by the BMA’s Ethics Committee.

Some key issues for third party funding surrogacy

- What are the medical – legal implications for a third party funder?

- What are the risks to the third party funder if the position if the host mother changes her mind and wishes to have an abortion?

- What are the risks to the third funder if the genetic parents change their mind or both parents reject the child?

- What are the risks to the third party funder is the surrogate mother becomes disabled or dies as a result of the pregnancy particular in relation to any existing children of the surrogate mother?

- What are the long term effects on the existing children of the surrogate mother?

- What are the long term effects on the surrogate mother?

- In considering equity - can the NHS justify funding IVF treatment for a woman not in clinical need of IVF?
IUI Policy
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<tr>
<td>Author:</td>
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<tr>
<td>Effective Date:</td>
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Derbyshire Intrauterine insemination - Commissioning Policy
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<td>19/05/15</td>
<td>Jilla Burgess-Allen</td>
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<td></td>
<td>David Fagg (Equality Lead, GEM)</td>
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<td></td>
<td>Steve Barr (Derbyshire Friend)</td>
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<td></td>
<td>Robyn Dewis (Derby City Public Health)</td>
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| 3     | Comments received from:           | 28/05/15   | Jilla Burgess-Allen     |
|       | Derbyshire CCGs Equality Steering Group |        |                         |

| 4     | Comments received from:           | 07/07/2015 | Jilla Burgess-Allen     |
|       | Vanessa Griffiths (SDCCG), and Claire Foreman (NHS England, Specialised Commissioning) |        |                         |

| 5     | Comments received from:           | 16/07/2015 | Jilla Burgess-Allen     |
|       | Clinical Policies Group (meeting held 9/7/15) |        |                         |
|       | Kate Brown (SDCCG)                |            |                         |

| 6     | Comments received from Derby Positive Support and Disabled People's Diversity Forum:- | 07/08/2015 | Jilla Burgess-Allen     |
|       | Comment: Should alcohol be included, since it affects fertility? |        |                         |
|       | Response: Alcohol is not included in the E.Mids IVF Policy so to be in line with that it has not been included in this policy. |        |                         |
|       | Comment: Should the policy cover a situation where testicular cancer affects male fertility or would this procedure not be appropriate in these circumstances? |        |                         |
|       | Response: fertility cryopreservation falls outside the scope of this policy. |        |                         |
|       | Comment: It seems hard for folks on a low income as they have to pay for 6 cycles before they qualify for any free help. It seems an awful lot of money to have to find if you are on a low income. |        |                         |
Introduction and Scope

The purpose of this commissioning policy is to set out Derbyshire CCGs' commissioning responsibilities and the criteria for access to NHS funding for intrauterine insemination.

This policy is an update of the existing Derbyshire County PCT "Commissioning Policy for Subfertility Services" published in December 2010 and has drawn on the revised NICE Clinical Guideline 'Fertility, assessment and treatment for people with fertility problems (CG156 February 2013). CG156 replaces the previous CG11 (2004), and includes updated recommendations regarding the effectiveness of intrauterine insemination (IUI).

This policy now covers Intrauterine Insemination (IUI) only, and should be read in conjunction with the East Midlands Commissioning Policy for In Vitro Fertilisation (IVF)/Intracytoplasmic Sperm Injection (ICSI) within tertiary Infertility Services (April 2014).

The scope of the NICE Guideline 156 and this policy makes it clear that it is intended for people who have a possible pathological problem (physical or psychological) to explain their infertility.

Epidemiology

NICE define infertility according to the period of time people should be trying to conceive after which it would be reasonable to initiate formal assessment and possible treatment.

Where the woman is of reproductive age and having regular unprotected vaginal intercourse two to three times per week, this period is 12 months.

Where the woman is aged over 36, the period is 6 months.

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1 A NICE evidence update (March 2015) included no further evidence relating to IUI
For same-sex couples, referral for assessment and possible treatment would be reasonable after failure to conceive after 6 cycles of AI\(^2\) within the 12 past months.

Around 84% of couples attempting to conceive are successful after trying for one year. After two years this figure rises to 92%. Female fertility declines with age and for women aged 38 about 77 out of every 100 who have regular unprotected sexual intercourse will get pregnant after 3 years.

At any point in time, the estimated prevalence of infertility is 1 in 7 couples in the UK.

The need for fertility assessment and treatment may increase due to the trend towards later first pregnancies and an increasing number of new partnerships later in adulthood. Demand is increasing due to increased public awareness of treatment possibilities. It is likely that there is unexpressed and/or unmet demand, particularly from women with secondary infertility (those who have conceived before but do not necessarily have a child).

**Causes of infertility**

Approximate proportions of principal causes based on studies of couples seeking treatment are given below. A significant proportion of couples will have more than one cause and the distribution varies between primary and secondary infertility.

- Unexplained infertility (no identified male or female cause) (25%)
- Ovulatory disorders (25%)
- Tubal damage (20%)
- Factors in the male causing infertility (30%)
- Uterine or peritoneal disorders (10%).

There is evidence that infertility causes considerable emotional stress and distress, which may affect many areas of couples' lives and can have significant deleterious impact on social and mental wellbeing.

**Types of fertility treatment**

There are three main types of fertility treatment: medical treatment (such as drugs for ovulation induction); surgical treatment (e.g. laparoscopy for ablation of endometriosis); and assisted reproduction.

Assisted reproduction techniques include:

- In vitro fertilisation (IVF)
- Intra-cytoplasmic sperm injection (ICSI)
- Donor insemination (DI), oocyte (egg) donation and cryo-preservation (oocytes and/or embryos)
- Intrauterine insemination (IUI)

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\(^2\) AI must be undertaken in a clinical setting with an initial clinical assessment and appropriate investigations
IUI is a form of treatment where faster sperm are separated from slower or non-moving sperm and then inserted into the uterine cavity around the time of ovulation. IUI can be carried out in a natural cycle, without the use of drugs, or the ovaries may be stimulated with oral anti-oestrogens or gonadotrophins. IUI can be undertaken using partner or donor sperm.

Over 50% of women aged under 40 years will conceive within 6 cycles of IUI, and of those who do not conceive within 6 cycles of IUI, about half will do so with a further 6 cycles (cumulative pregnancy rate over 75%).

**Figure 1.**

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<tr>
<th>Woman's age</th>
<th>IUI using thawed semen</th>
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<tr>
<td></td>
<td>6 cycles</td>
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<tr>
<td>30-34yrs</td>
<td>63%</td>
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<tr>
<td>&gt;34yrs</td>
<td>50%</td>
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The data in figure 1 above reflect results using insemination with donor semen and not partner semen. If a partner’s sperm is to be used then fresh sperm would be preferable.

**Establishing eligibility under this Policy**

All couples are eligible for consultation and advice in primary care. Where a woman is of reproductive age and having regular unprotected vaginal intercourse two to three times per week, failure to conceive within 12 months should be taken as an indication for further assessment and possible treatment.

If the woman is aged 36 or over then such assessment should be considered after 6 months of unprotected regular intercourse, since her chances of successful conception are lower and the window of opportunity for intervention is narrower.

A summary of the eligibility criteria for IUI for different patient groups is given in figure 2.
Couples must meet the referral criteria set out in Figure 3 before being referred by their GP for further investigation and assessment for assisted fertility treatment.

IUI, either with or without ovarian stimulation, should not be routinely offered to people with unexplained infertility, mild endometriosis or ‘mild male factor infertility’, who are having regular unprotected sexual intercourse, except in exceptional circumstances. NICE no longer recommends IUI for these groups of patients because a review of the literature concluded that IUI without stimulation is no better than expectant management (Bhattacharya et al. 2008; Wordsworth et al. 2011). It is unclear whether IUI with stimulation is more effective than expectant management for these groups; however it is likely to increase the risk of multiple pregnancies, which is the single biggest risk of fertility treatment.

When people have social, cultural or religious objections to IVF, who have an underlying fertility problem, the option of IUI will be discussed as part of the assessment and treatment in the NHS.
### Figure 3: Referral Criteria

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<th>Category</th>
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<tr>
<td>Woman’s Age</td>
<td>Should be referred by the age of 39 years</td>
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<tr>
<td>Man’s Age</td>
<td>55 years or younger</td>
</tr>
<tr>
<td>Woman’s BMI</td>
<td>Within the range of 19-30</td>
</tr>
<tr>
<td>Man’s BMI</td>
<td>BMI &lt;35</td>
</tr>
<tr>
<td>Welfare of Child</td>
<td>The welfare of any resulting children is paramount. In order to take into account the welfare of the child, the centre should consider factors which are likely to cause serious physical, psychological or medical harm, either to the child to be born or to any existing children of the family. This is a requirement of the licensing body, Human Fertilization and Embryology Authority.</td>
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<tr>
<td>Family Structure</td>
<td>No living children from current or previous relationship(s), including adopted children, but excluding foster children. There needs to be an explicit and recorded assessment that the social circumstances of the family unit have been considered within the context of the assessment of the welfare of the child.</td>
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<td>Smoking</td>
<td>Neither partner must be a current smoker. Ex-smokers must have been quit for at least 28 days before treatment commences and must continue to be non-smoking throughout treatment.</td>
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<tr>
<td>Sterilisation</td>
<td>Sterilised patients are not eligible for NHS funded treatment.</td>
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In line with NICE guidance, unstimulated IUI may be considered as a treatment option in the following groups as an alternative to vaginal sexual intercourse:

- People who are using partner or donor sperm and who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem\(^4\)
- People in same-sex relationships

For people in the above specific groups who have not conceived after 6 cycles of donor or partner insemination (self-funded\(^5\)), despite evidence of normal ovulation, tubal patency and semen analysis, a further 6 NHS funded cycles of unstimulated IUI should be offered before IVF is considered. For the purpose of access to NHS services, donor or partner insemination should be undertaken in a clinical setting with an initial clinical assessment and appropriate investigations.

Same-sex couples considering surrogacy are referred to the EMSCG Policy for Surrogacy (2010). This Policy states that the NHS “will not provide routine funding for the medical treatment required to give effect to a surrogacy arrangement”.

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\(^3\) NICE recommends men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility.

\(^4\) Where psychosexual problems prevent vaginal intercourse the couple should, in the first instance, be referred for psychosexual counselling.

\(^5\) The CCG will not fund the initial 6 AI cycles but will fund access to a clinical consultation to discuss options for attempting conception, further assessment and appropriate treatment. The cost to couples self-funding AI is typically between £500 and £1000 per cycle.
Fertility treatment for people living with HIV is the commissioning responsibility of CCGs. We will fund IUI for people who are clinically indicated to receive IUI following a successful sperm washing procedure where the man is HIV positive. The rationale for funding initial rounds of IUI for this group of patients but not those above (who are unable to have vaginal intercourse due to clinically diagnosed physical disability or psychosexual problem, and people in same-sex relationships) is that IUI for couples where the male is HIV positive serves to prevent transmission of HIV to the woman and the child.

- Sperm washing should be offered to couples where the man is HIV positive and either he is not compliant with HAART or his plasma viral load is 50 copies/ml or greater, and who meet the criteria in table 1.
- Male partners who are hepatitis C (HCV) positive have a low likelihood of transmitting the virus through sexual intercourse (approximately 2%) and NICE state there is insufficient evidence about the value of sperm washing to reduce that risk even further; partners of individuals with hepatitis B should be vaccinated before fertility treatments begin and sperm washing is not be necessary.

Patients who fail to achieve a pregnancy using IUI/DI will be considered for IVF.

**Exceptional circumstances**

Cases may be considered via the CCG’s Individual Funding Request route but must demonstrate robust, clinical exceptionality.

**Due Regard**

This policy has been reviewed in relation to having due regard to the Public Sector Equality Duty (PSED) of the Equality Act 2010 to eliminate discrimination, harassment, victimisation; to advance equality of opportunity; and foster good relations between the protected groups.

**References**

- Derbyshire County PCT Commissioning Policy for Subfertility Services, December 2010
- EMSCG Policy for Surrogacy (2010)
- HFEA (Human Fertilisation & Embryology Authority) [http://www.hfea.gov.uk/IUI.html](http://www.hfea.gov.uk/IUI.html)
Policy Statement for the Commissioning of Dry Needles
**Policy Title:** Policy Statement for the Commissioning of Dry Needles

**Supersedes:**

**Description of Amendment(s):**

**This policy will impact on:** Patients of ND CCG Membership Practices

**Financial Implications:** No financial implications

**Policy Area:** All CCG Community

**Version No:** V1

**Issued By:** Joint Clinical Commissioning Policy Advisory Group

**Author:** Emily Smith, Public Health

**Effective Date:** November 2014

**Review Date:** November 2016

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| Governing Body Assurance Committee |

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Overall Recommendation

There is currently insufficient evidence to recommend funding dry needling for chronic musculoskeletal pain.

Introduction

This statement sets out a recommendation to CCGs in Derbyshire on the funding of dry needling (insertion of needles into muscles to manage chronic musculoskeletal pain). It is based on a review of the most up-to-date evidence available at the time of writing. This review will focus on the use of dry needling to treat musculoskeletal pain but not Achilles tendon problems.

Overview

There is no consensus definition of, or technique for, dry needling. It involves inserting needles into muscles to help with musculoskeletal pain. Some practitioners insert the needles into so-called “trigger points” (bands of tense muscle fibres) in the area that is causing pain; others insert the needles away from the area that is causing pain. The most commonly described indication for dry needling is the treatment of myofascial pain syndrome, which cause musculoskeletal pain due to trigger points (“hyperirritable spots within a taut band of contractured skeletal muscle fibers that produce local and/or referred pain when stimulated”).

Patient group

Dry needling is used for the treatment of myofascial pain syndrome, as well constriction of movement caused by excess scar tissue or adhesions. It has also been used to treat tendinopathy.

Estimated level of need

It is difficult to give a precise estimate of the potential level of need for this service. It is provided by some NHS providers, but the author of this report could not locate any national data on its use. There is also limited data on the prevalence of myofascial pain syndrome, which appears to be the most common indication. It has been estimated that around 7 million people have a chronic musculoskeletal health condition in the UK.

Evidence review of clinical effectiveness

A literature search was undertaken to identify high quality evidence (defined as systematic reviews and/or meta-analyses) on the effectiveness of dry needling. Seven reviews were identified that met this criterion:

- Ong and Claydon 2014 conducted a systematic review and meta-analysis comparing lidocaine injections with dry needling for neck and shoulder pain, and concluded that there was no significant difference between the two therapies.
- France et al 2014 undertook a systematic review looking at the efficacy of dry needling as an adjunct to physiotherapy for the treatment of tension headaches. It concluded that “there is insufficient evidence to strongly advocate for the use of dry needling.”
• Kietrys et al 2013 undertook a systematic review and meta-analysis9 of the efficacy of dry needling in treating chronic shoulder and neck pain caused by a variety of diagnoses (these varied across studies). When comparing placebo with dry needling, the meta-analysis showed that although dry needling was significantly more effective than a placebo initially, at 4 weeks, there was no significant difference between placebo and dry needling groups. When dry needling was compared to other active treatments, the meta-analysis of the initial effects of intervention favoured other treatments initially; at 4 weeks there was no significant difference between the two groups in the meta-analysis. Within this last group of trials, there was a wide variation in the outcomes of individual studies and active treatments used (which included botox injections, lidocaine injections and acupuncture).

• Cotchett et al 2010 carried out a systematic review13 of the effectiveness of dry needling at managing plantar fasciitis; they concluded that there was “limited” evidence for its use here. They noted the poor methodological quality of many of the studies.

• Tough et al 2009 conducted a systematic review and meta-analysis examining the effectiveness of dry needling at treating myofascial pain syndrome10. This did not find any statistically significant difference between dry needling and placebo.

• A Cochrane review (Furlan et al 2005)11 found “limited evidence” that dry needling might be effective as an adjunct to conventional treatment of low back pain, but that overall “no clear recommendations can be made because of small sample sizes and low methodological quality of the studies”.

• Cummings et al 2005 concluded in their systematic review12 that there was insufficient evidence to judge whether dry needling was more effective at managing myofascial pain than placebo.

Evidence review of cost effectiveness

No evidence was found regarding the cost effectiveness of dry needling.

Summary

In summary, dry needling is a technique that has been used for the management of musculoskeletal pain. A review of the evidence base shows that there is insufficient evidence to recommend its use in routine practice currently.

References

4. Staffordshire and Stoke on Trent Partnership NHS Trust. GP Briefing September 2014. Available from: http://www.google.co.uk/url?url=http://www.staffsrespondsccg.nhs.uk/index.php%3Fid%3D153%26type%3D0%26juSecure%3D1%26locationData%3D153%253A751%26juHash%3D9a4b2fc3577c3655d1da02a5667360cf447b3b70


Eye Gazer Policy
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Policy for the Commissioning of Eye-tracking Communication Devices in Adults

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1 Introduction

This is the policy of NHS Derbyshire CCGs (North Derbyshire CCG, Hardwick CCG, Southern Derbyshire CCG and Erewash CCG) to commission eye tracking communication devices for adults. It will be applied in conjunction with the NHS Derbyshire CCGs Individual Funding Request Policy and reflects the principles set out in the NHS Derbyshire CCGs Ethical Framework for Decision Making.

2 Scope

This policy sets out the criteria for the commissioning of eye tracking communication devices as an assistive communication aid in adults. The criteria are based upon clinical evidence and clinical expert opinion.

This policy does not consider the commissioning of eye tracking communication devices in children, or their use during neuropsychological assessment.

3 Definitions

Eye Tracking Communication Devices (ETCD, often called eye gazers) are communication aids that allow individuals with extremely limited motor function and loss of speech to communicate through the tracking of their eye movements. Eye tracking communication devices are able to detect and interpret patients’ eye movements through use of an infra-red camera. In combination with appropriate software and a display, patients are able to communicate by pointing and holding their gaze on various commands displayed on the monitor. Use of eye tracking communication devices can assist in addressing the severe impact on dependence and quality of life resulting from a range of conditions.

4 Principles

Commissioning decisions by the NHS Derbyshire CCGs are made in accordance with the Guiding principles and the commissioning principles set out in appendix A and in the NHS Derbyshire CCGs Individual Funding Request Policy.

5 Exceptionality

NHS Derbyshire CCGs will consider individual cases for funding outside this commissioning policy in accordance with the Individual Funding Request Policy which defines exceptionality and sets out a decision making framework for determining these cases.

6 Criteria for commissioning

Eye tracking communication devices are an example of an Augmentative and Alternative Communication (AAC) Aid, and responsibility for commissioning AAC is shared between CCGs and NHS England. CCGs are responsible for commissioning non-specialised AAC equipment, with NHS England having direct responsibility for assessment and provision of specialised AAC. It is the complexity and severity of an individual's condition, and the expertise required to assess and support and provide and maintain equipment to the individual that defines a requirement for a specialised AAC service, as opposed to the nature of the equipment itself.
Individuals should meet all of the following criteria to be considered for the provision of eye tracking communication devices under this policy:

- aged over 18 years
- registered with a GP practice within Erewash, Hardwick, North Derbyshire or Southern Derbyshire CCGs
- have a neurodegenerative condition, acquired brain injury or stroke that has resulted in the individual having severe loss of motor control and loss of speech
- have undertaken an augmentative and alternative communication assessment with the Speech and Language Therapy service at Derbyshire Community Health Services that has identified a need for the use of eye tracking communication devices

Inclusion criteria for assessment by the specialist AAC service commissioned by NHS England are individuals who:

- are in need of complex assessment (but not necessarily complex equipment)
- are able to understand the purpose of a communication aid
- have developed beyond cause and effect understanding
- require communication technology needs beyond the competence of local AAC service
- have some or all of the following:
  - severe physical disability, especially of upper limbs
  - additional sensory impairment to the communication impairment
  - in need of specialist switch access, which may need to be bespoke
  - in need of a device that integrates spoken and written communication, as well as environment control
  - multiple disabilities which in combination impact on the individual’s ability to communicate
  - experience of using low tech AAC which is insufficient to enable them to realise their communicative potential

It is expected that the largest client group eligible for use of eye tracking communication devices under this policy will be individuals with Motor Neurone Disease.

7 Patient pathway

Patients requiring alternative and augmentative communication (AAC) devices, including eye tracking communication devices, should be referred to the Speech and Language Therapy service at Derbyshire Community Health Services for an initial assessment of need. It is unlikely that patients will be identified as needing eye tracking communication devices following an initial assessment, and that their immediate needs can be met by alternative devices. However, timely re-assessments will be required to ensure changing needs are accounted for, and provision of eye tracking communication devices should be considered during re-assessment.

If a need for an eye tracking communication device is identified then the Speech and Language Therapy service at Derbyshire Community Health Services should take advantage of trials and assessment centres offered by manufacturers to determine the suitability of different systems available for that individual.
If assessing the communication needs of an individual is beyond the capability of the Speech and Language Therapy service at Derbyshire Community Health Services, then the individual should be referred to the specialist AAC service. Within the East Midlands, this is currently provided by Lincolnshire Community Health Services NHS Trust. The specialist service will review the individual, and determine whether the individual will require provision of specialised assessment or support, or whether provision by the local team is sufficient to meet the individual’s needs.

8 Epidemiology

Local information suggests that between eight and ten adults across Derbyshire require provision of an eye tracking communication device each year. Numbers have increased slightly in recent years, primarily due to an increasing awareness of available technology amongst patient groups, but also due to an aging population.

A recent report estimated that 0.05% of the adult and child population have a need for specialised AAC. No estimates were provided as to the proportion that would require eye tracking communication devices.

It is expected that local teams will manage the needs of 90% of the local population requiring AAC, with the remaining 10% managed jointly between local services and specialised AAC services. Extrapolating this to local need for eye tracking communication devices would suggest that the majority of provision should be directly by Derbyshire Community Health Services, with only one or two cases per year requiring NHS England commissioned specialist assessment and provision.

9 Evidence-base

There is a lack of guidelines on the management of individuals who may require eye tracking communication devices. Guidelines on the management of individuals with motor neurone disease acknowledge the importance of managing communication difficulties within multidisciplinary care, but highlight the lack of evidence on the ways to optimise communication. A NICE guideline on the assessment and management of motor neurone disease is due for publication in 2016, with communication difficulties included as a key issue that will be covered during the development of the guidance.

The available evidence on the effectiveness of eye tracking communication devices comes from studies of low quality with small numbers of participants. These studies suggest that use of eye tracking communication devices may improve quality of life and reduce levels of depression. No studies have been identified that assess the cost-effectiveness of eye tracking communication devices. Details of individual studies are provided in Appendix B.

Adverse effects reported through use of eye tracking communication devices include bloodshot eyes and tiredness. In addition, use of an eye tracking communication device may not be suitable in individuals with involuntary movements of eyelids or difficulties in holding eyelids open.

10 Financial considerations

Eye tracking communication devices cost approximately £10,000, and there may be associated additional costs, for example a mount to attach the kit to a wheelchair. Recently, stand-alone eye-
tracking devices that can be connected to personal laptops or computers have come onto the market, priced at approximately £2,000.

The equipment is re-usable and therefore can be reset for new users. However, it should be noted that the equipment and software may become outdated as eye gazer technology continues to develop. Estimating the average length of use is unpredictable due to the wide range of conditions where eye tracking communication devices are required.

Based on current level of need, the estimated costs across the Derbyshire CCGs will be between £80,000 and £100,000 per year. However, with the possibility of re-use, and cheaper devices appearing on the market, annual costs may be lower than this.
Appendix A: Guiding and Commissioning Principles adopted by Derbyshire Clinical Commissioning Groups

Guiding principles

All services will be person-centred

We will work in partnership with people needing care and their families and carers to provide care as close to the person’s home as possible, and when appropriate support them to access the right care away from home.

Care will be provided flexibly

We will listen to and understand the person’s complete needs and meet them by using all services and resources available. We will ensure that we will co-ordinate care across health, social care and voluntary services to ensure people receive the right care from the right service at the right time.

Assumptions will be challenged

We will have the courage to make changes for the better that will improve the patient experience and obtain the best value for money. We will embrace innovation and find new approaches to care based on sound evidence. We will commit to monitoring and publishing patient experience data to be accountable to those who use our services.

People will be treated with dignity and respect

We respect and value the people who use and work in health and social care services in Derbyshire and we will invest resources to support the health and well-being of our communities.

We will plan and deliver services partnership

We will actively seek and listen to the views of people who use and work in health and social care in Derbyshire so that we can plan and deliver services in partnership and be accountable to them.

Healthy lifestyles will be promoted

We will support people to help them to make an informed choice about lifestyle and services and identify and provide extra support for those who need and want to make positive lifestyle changes.

Commissioning principles

- the CCGs requires clear evidence of clinical effectiveness before NHS resources are invested in the treatment
- the CCGs requires clear evidence of cost effectiveness before NHS resources are invested in the treatment
- the cost of the treatment for this patient and others within any anticipated cohort is a relevant factor.
• the CCGs will consider the extent to which the individual or patient group will gain a benefit from the treatment
• the CCGs will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
• the CCGs will consider all relevant national standards and take into account all proper and authoritative guidance
• where a treatment is approved, the CCGs will respect patient choice as to where a treatment is delivered
Appendix B: Summary of studies that assess the effectiveness of eye tracking communication devices

Caligari et al (2013) recruited 35 individuals with MND who were already using an ETCD. vii The authors reported significantly reduced communication problems when using ETCD compared to using no device or an eye transfer board, including improving the ability to convey a message, feelings or opinions and be involved in treatment decisions. In addition, the authors reported significantly improved Quality of Life scores amongst users. Outcomes were assessed through use of questionnaires and the investigators asked participants to retrospectively score experiences prior to using an ETCD and compare this to current use of ETCD. Due to the expense of ETCD, the authors recommend that ETCD technology may be most effective for individuals with extremely limited mobility, and those individuals who retain some hand, foot or head movement should utilise other methods of assistive communication.

Hwang et al (2014) recruited 20 individuals with MND, and arbitrarily divided participants into two groups: a group that used an ETCD for six months; and a group that continued to use a phonetic board for communication. viii After six months, users of ETCD reported significantly higher quality of life and significantly lower depression scores compared to non-users. However, no results were reported that assessed the impact of ETCD by comparing Quality of Life and mood scores before and after the study period in each group.

Calvo (2009) reported that use of ETCD improved life conditions and management activities conducted by care-givers in nine patients with MND. In addition, quality of life and levels of depression scores were improved in seven of the patients after using an ETCD. It is unclear whether participants were assessed for mood and quality of life at baseline. ix
References

ii Office of the Communication Champion and Council (2011) Specialised AAC provision: Commissioning national services
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Commissioning of Sensory Integration Therapy

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**Overall Recommendation**

There is insufficient evidence to suggest that Sensory Integration Therapy is a clinically effective intervention which should be considered as a stand-alone service.

Sensory Integration Therapy is not commissioned by health services in Derbyshire.

Occupational Therapy services for children and young people are commissioned, based on national guidance and local need.

**Introduction**

This statement forms part of the policy on a range of treatments that the Clinical Commissioning Groups in Derbyshire are asked to fund. It has been developed based on an analysis of evidence of clinical and cost effectiveness for the specified treatment, ensuring the consistent and transparent approach to commissioning decisions across the whole commissioning portfolio.

This statement relates to Sensory Processing Difficulties and Sensory Integration Therapy.

**Overview of Sensory Integration Therapy**

Sensory integration therapies are often used by Occupational Therapists in the treatment of children and young people with developmental and behavioural disorders. Activities that are encompassed within the sensory integration approach include the use of swings, balls, children’s play equipment and other specially designed therapeutic or recreational equipment. Sensory-based therapies provide, vestibular, proprioceptive, auditory, and tactile inputs (explanations given in box 1 below).

**Box1.**

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<tr>
<th><strong>Tactile Activities:</strong></th>
<th>Incorporate the sense of touch and feeling into the procedures such as texture toys, and finger painting.</th>
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<td><strong>Vestibular</strong> (over or under sensitive to balance and movement sensations) Activities:</td>
<td>Involves a child's perception of movement caused by the inner ear being stimulated because of the position of the head. Examples of vestibular activities include using a trampoline and playing spinning games.</td>
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<td><strong>Proprioceptive</strong> (difficulty interpreting sensations from the muscles, joints, ligaments, and tendons) Activities:</td>
<td>These use procedures that incorporate body awareness which comes from the body’s muscles, ligaments, and joints. Some examples of proprioceptive activities include cocooning, hiking trips, and relatively heavy weight load activities.</td>
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<td><strong>Auditory Activities</strong> (Relates to the ability to understand language and social interactions):</td>
<td>This involves the use of sound and language to aid interpretation and understanding amongst participants.</td>
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Evidence review of clinical effectiveness

There have been a large number of studies conducted on sensory integration since its inception in the 1970’s. The majority of these studies are small scale and of poor methodological validity and produce a variety of conflicting outcomes (Schaaf et al, 2012, Devlin et al, 2012, Polatajko & Cantin 2010, Roley et al 2009 and Wuang et al 2009). The most comprehensive document available related to sensory integration therapy is from the American Academy of Paediatrics (2012). This text is used extensively to inform this section of the policy statement.

SIGN (2007) state that there was insufficient evidence to support any recommendation about Occupational Therapy for Autism Spectrum Disorder (ASD) this includes specific interventions such as sensory integration. Furthermore SIGN highlight that children and young people affected by ASD may benefit from occupational therapy for generic indications, for example providing advice and support in adapting environments, activities and routines in daily life.

The SIGN guidance is further supported by more recent research and policy work undertaken by the American Academy of Paediatrics (2012) who look at sensory integration therapy from a broader perspective than ASD. The American Academy of Paediatrics state that:

‘Because there is no universally accepted framework for diagnosis, sensory processing disorder generally should not be diagnosed. Other developmental and behavioural disorders must always be considered, and a thorough evaluation should be completed. Difficulty tolerating or processing sensory information is a characteristic that may be seen in many developmental behavioural disorders, including autism spectrum disorders, attention-deficit/hyperactivity disorder, developmental coordination disorders, and childhood anxiety disorders.’ (p. 1186)

Occupational Therapy with the use of some sensory-based therapies may be acceptable as one of the components of a comprehensive treatment plan managed with the professional setting. However as the American Academy of Paediatrics (2012) go on to caution; parents should be made aware of the very limited supporting evidence around the effectiveness of sensory integration therapy and families should be taught how to evaluate the effectiveness of the therapy.

Policy Statement

Based on the review of evidence It is concluded that there is insufficient evidence to suggest that Sensory Integration Therapy is a clinically effective intervention which should be considered as a stand-alone service.

Sensory Integration Therapy is not commissioned by health services in Derbyshire.

Occupational Therapy services for children and young people are commissioned in Derbyshire, based on national guidance and local need.
References


Policy Statement for the Commissioning of Mechanical Insufflation / Exsufflation – MI-E (Cough Assist Device) for Neuromuscular Disorders and Cervical Spinal Cord Injury patients

Supersedes:

Description of Amendment(s):

This policy will impact on: Patients of ND CCG Membership Practices

Financial Implications: No financial implications

Policy Area: All CCG Community

Version No: V1

Issued By: Joint Clinical Commissioning Policy Advisory Group

Author: Dean Wallace, Specialty Registrar in Public Health
        Suzanne Meredith, Specialty Registrar in Public Health

Effective Date: March 2014

Review Date: March 2016

APPROVAL RECORD

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Policy Statement for the Commissioning of Mechanical Insufflation / Exsufflation – MI-E (Cough Assist Device) for Neuromuscular Disorders and Cervical Spinal Cord Injury patients

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**Overall Recommendation**

The lack of robust clinical and cost-effectiveness evidence means that cough assist devices should not be routinely commissioned by the CCG.

This policy should be reviewed regularly to take account of the expanding evidence base.

**Introduction**

Respiratory complications are a leading cause of mortality and morbidity for patients with neuromuscular disorders (NMD), where muscle weakness and progressive chest deformities can affect their respiratory function. Comparable problems can also be experienced by people with spinal cord injury. Although cervical spinal cord injuries represent a diverse spectrum the potential impact of the resultant muscle weakness on respiratory function is similar.

Progressive weakening of the respiratory muscles can reduce the ability to cough, and therefore make it difficult to clear pulmonary secretions, which can lead to airway obstruction, increased work to breathe, hypoxia and respiratory failure. Long term retention of secretions can lead to infections, atelectasis and chronic lung disease (Homnick, 2007)

**Background to the technology**

The identification of measures to optimise cough efficacy is key to improving the quality of life and preventing morbidity in people with NMDs (Morrow et al, 2013). There are a range of manual methods currently used by physiotherapists to assist secretion clearance and augment coughing (Anderson 2005, Finder 2010), which have been shown to be effective.

Mechanical insufflation-exsufflation (MI-E) uses a machine to apply a positive pressure into the airways followed by an abrupt change to negative pressure to simulate a natural cough. This can be applied via a non-invasive method (via the nose or mouth) or via a tracheostomy.

**The Evidence**

MI-E has been shown to enhance peak cough flow which is necessary for effective secretion clearance (compared to other manual methods) in some small short term observational studies (Morrow et al 2013; Anderson 2005; Bach 1993; Chatwin 2003; Fauroux 2008).

Other considerations include safety issues associated with applying pressure to the weakened chest wall and lungs, such as an increased risk of pneumothorax (Homnick 2007), the tolerance of the method and the potential for improved quality of life of the patient. Some small observational studies have reported MI-E to be well tolerated (Fauroux 2008) and “mostly safe” and effective in preventing and treating pulmonary complications (Miske 2004) but an adverse effect of fatigue has also been reported (Chatwin, 2009). There are also ongoing debates over the most effective and safe pressures to use for different age groups.

The studies that have been undertaken indicate that there may be potential for MI-E to be beneficial for some patients with NMD at certain stages of progression. However, these were small observational studies or case studies and are considered to be of low quality in terms of the evidence base. No prospective RCTs have been identified that measure clinically relevant short or long term outcomes compared to other cough augmentation interventions (Morrow et al 2012) and therefore there is no robust evidence to support the use of MI-E for patients, either in a chronic or acute setting. NICE has not yet reviewed the use of MI-E. Therefore the body of evidence does not allow any conclusions to be reached regarding the efficacy or safety of MI-E in people with a NMD.
There are costs involved in terms of the equipment and consumables. There are currently no economic evaluations of the therapy or identified outcomes such as frequency of exacerbations, hospitalisation, duration of stay or quality of life. In recognition of this, in 2013, the National Institute for Health Research published a request for applicants to undertake a feasibility study for an RCT to address the research question “What is the effectiveness and cost-effectiveness of Mechanical Insufflation-Exsufflation devices when compared to other methods of sputum clearance commonly used in children and young people with neuromuscular disease?”.

**Guidelines**

A range of guidelines have recommended MI-E as part of a package of respiratory recommendations, including manual physiotherapy techniques, to support patients with NMD, particularly for those who are very weak, with loss of bulbar function or who cannot co-operate with manual cough assist techniques.

These recommendations either acknowledge the lower level of quality of evidence they are based on or they are based on expert opinion and consensus in the absence of research evidence.

The use of the MI-E is supported as part of the respiratory treatment for people with NMD in the following:


Ching H. Wang, Richard S. Finkel, Enrico S. Bertini, Mary Schroth, Anita Simonds, Brenda Wong, Annie Aloysius, Consensus Statement for Standard of Care in Spinal Muscular Atrophy *J Child Neurol* 2007; 22; 1027. Available at http://jcn.sagepub.com/cgi/content/abstract/22/8/1027

NHS England’s Service Specification for Neurosciences: Specialised Neurology (Adult) D04/S/a – Annex B includes children 2013 (it is unclear on what evidence base this recommendation is made)
Policy Statement

Overall, there is currently insufficient research evidence either for or against the use of MI-E for patients with NMD or spinal cord problems. Guidance from a range of professional bodies has supported its use, based on low quality evidence or expert opinion. Further research is needed to establish the effects relating to reducing infections, safety, its use in the longer term and its cost effectiveness. This has started to be addressed at a national level, but will take some time to be available. A regular review of the evidence base is recommended.

There may be exceptional circumstances where a clinician can demonstrate that a patient can derive significantly greater benefit from the technology than other patients. In these circumstances please read the Individual Funding Request (IFR) policy and complete the relevant form.
References


BTS / ACPRC: Joint guidelines for the Physiotherapy management of the adult, medical, spontaneously breathing patient,*Thorax* 2009;64:i1-i52 doi:10.1136/thx.2008.110726 available at http://thorax.bmj.com/content/64/Suppl_1/i1.full


Ching H. Wang, Richard S. Finkel, Enrico S. Bertini, Mary Schroth, Anita Simonds, Brenda Wong, Annie Aloysius, Consensus Statement for Standard of Care in Spinal Muscular Atrophy *J Child Neurol* 2007; 22; 1027. Available at http://jcn.sagepub.com/cgi/content/abstract/22/8/1027


Policy Statement for the Commissioning of Trigger Point Injections
Policy Statement for the Commissioning of Trigger Point Injections
| Policy Title: | Policy Statement for the Commissioning of Trigger Point Injections. |
| Supersedes: | |
| Description of Amendment(s): | |
| This policy will impact on: | Patients of ND CCG Membership Practices |
| Financial Implications: | No financial implications |
| Policy Area: | All CCG Community |
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| Issued By: | Joint Clinical Commissioning Policy Advisory Group |
| Author: | Emily Smith, Public Health |
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Policy statement for the commissioning of trigger point injections

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Overall Recommendation

There is insufficient evidence to recommend funding trigger point injections on a routine basis.

Introduction

This statement sets out the policy of CCGs in Derbyshire on the funding of trigger point injections (injections of active substances into “trigger points” to manage chronic musculoskeletal pain). It is based on a review of the most up-to-date evidence available at the time of writing. It does not consider “dry-needling”, which is the insertion of needles into trigger points without the injection of any substance.

Overview of Trigger Point Injections

Trigger point injections are a technique used to aid in the management of chronic musculoskeletal pain. Trigger points are “palpable, tense bands of skeletal muscle fibres”. The cause of trigger points is unclear. It has been suggested that they cause pain due to abnormally sensitized pain nerve endings. Trigger point injections use a variety of substances, such as local anaesthetic, which are then injected into the trigger points to relieve pain, possibly either through the effect of the injected chemical or through the physical effects of the injection needle entering the muscle. There is no single established technique for carrying out trigger point injections.

Patient group

Trigger point injections have been used for a variety of conditions, including chronic back pain, neck pain, headaches and myofascial pain syndrome (this is a chronic pain syndrome which causes muscular pain centred on trigger points). The injections are usually given by pain specialists in a secondary care setting.

Estimated level of need

Around 7 million people in the UK report a chronic musculoskeletal health problem. Around 10% of people in England report a long term back problem. It is difficult to know how many people have their pain managed by trigger point injections; there is no routine data available and the service is not available in all areas as some CCGs do not commission the service due to lack of a robust evidence base.
Evidence review of clinical effectiveness

There are a number of systematic reviews of trigger point injections. A systematic review of the literature on the effectiveness of trigger point injections for managing chronic, non-malignant musculoskeletal pain concluded that the effectiveness of trigger point injections is still unclear⁴. A second systematic review looking at the use of trigger point injections in chronic lower back pain found “insufficient” evidence for their use⁸.

There are three Cochrane reviews that examine a variety of indications for trigger point injections. Staal et al carried out a systematic review of injection therapy for sub-acute and chronic low back pain, concluding that there was not enough evidence in favour of the use of trigger point injections⁵. Soares et al have published a review of the use of botulinum toxin injections to treat myofascial pain syndrome, which found insufficient evidence to support its use in trigger point injections⁶.

The third review, which looked at treatments for mechanical neck disorders⁷, found “moderate” evidence in favour of benefit for the use of lidocaine to treat chronic pain in the neck, based on three small randomised controlled trials. This review concluded that these trials would need to be replicated in bigger trials with better methodology for their findings to be more widely adopted.

On closer examination, three RCTs are included in this review:

- One RCT compares neck stretches, lidocaine injections and botox injections, finding that lidocaine and botox are equally effective, and that both are more effective than neck stretches¹⁰. As the same review concludes that there is moderate evidence against the effectiveness of botox injections, it is difficult to use this study as evidence of benefit for lidocaine injections. It is possible that the effect seen with lidocaine and botox is due to their effectiveness as an active placebo. The study was scored poorly (1/5) on the Jadad criteria (a marker of methodological quality).
- One RCT compares dry needling with lidocaine injections¹¹; this found lidocaine injections to be more effective than dry needling. However, the study does not differentiate between patients with acute and chronic neck pain, making it difficult to interpret its findings⁴, and it only provides outcomes at 2 weeks. This study was scored 3/5 on the Jadad scale by the reviewers.
- The third RCT compared neck stretches, ultrasound with neck stretches and lidocaine injections with neck stretches¹². Ultrasound and lidocaine injections were more effective than neck stretches alone, but there was no difference between ultrasound and lidocaine injections. This study again was of poor methodological quality, being rated 1/5 on the Jadad criteria by reviewers.

Therefore, the evidence contained in this review is limited. Two RCTs should arguably not be considered due to poor methodological quality¹⁰,¹², whilst the third contains a heterogeneous patient group and no information on long-term outcomes.

Evidence review of cost effectiveness

No studies of cost-effectiveness were identified.

Summary

Trigger point injections are used to help manage chronic musculoskeletal pain in a number of muscle areas. However, there appears to be limited evidence at the moment to support their widespread use. Therefore, trigger point injections should not be funded routinely.

References

9. http://www.staffordsurroundsccg.nhs.uk/commissioning/policies/clinical%3FeID%3Ddam_frontend_push%26docId%3D123&rt=j&fm=1&q=&esrc=s&sa=U&ei=ZfiPVOW6Os7T7Abx8YHIBg&ved=0CBkQFjAB&usg=A FQjCNFBP09h_qNexPmlJSSPPYgw-o3fkg Accessed 28/9/14