New Clinical Interventional Procedures Policy
<table>
<thead>
<tr>
<th>Policy Title:</th>
<th>New Clinical Interventional Procedures Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Summary:</td>
<td>This document sets out East Cheshire NHS Trust’s policy to ensure compliance by medical practitioners of the Trust, with HSC 2003/011 “The Interventional Procedures Programme” issued on the 13th November 2003.</td>
</tr>
<tr>
<td>Supersedes:</td>
<td>V5</td>
</tr>
</tbody>
</table>
| Description of Amendment(s): | This policy has been updated with the following minor amendments:  
- Changes to responsibilities  
- Reference to business units changes to service lines |
| This policy will impact on: | The introduction of New Clinical Interventional Procedures |
| Policy Area: | Trustwide |
| Version Number: | V5.1 |
| Effective Date: | April 2016 |
| Issued By: | Associate Medical Director (Clinical Effectiveness) |
| Review Date: | April 2019 |
| Author: | Fiona Smith, Head of Integrated Governance |
| Clinical Effectiveness, |

**APPROVAL RECORD**

<table>
<thead>
<tr>
<th>Committees / Group</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultation &amp; Approval</td>
<td>CARE (Clinical Audit Research &amp; Effectiveness) Group</td>
</tr>
<tr>
<td>11/03/2016</td>
<td>April 2016</td>
</tr>
</tbody>
</table>
Contents:

1.0 Policy Statement 4
2.0 Organisational Responsibilities and Duties 4
3.0 Planning and implementation 5
4.0 Process 5
5.0 Measuring Performance 6
6.0 Audit 6
7.0 Review 6
8.0 Bibliography 6
Appendix 1 7
   New Clinical Interventions Procedure Application Form
Appendix 2 9
   Equality Analysis Impact Assessment Tool
NEW CLINICAL INTERVENTIONAL PROCEDURES POLICY

1. Policy Statement
This document sets out East Cheshire NHS Trust’s policy to ensure compliance by medical practitioners of the Trust, with HSC 2003/011 “The Interventional Procedures Programme” issued on the 13th November 2003.

2.0 Organisational Responsibilities and duties

2.1 The Chief Executive:
Has overall responsibility for the implementation of National Guidance within the Trust.

2.2 The Medical Director has Trust Board responsibility for all aspects of this policy, including ratification.

2.3 The Associate Medical Director (Clinical Effectiveness) is responsible for advising on the clinical aspect of this policy

2.4 The Director of Corporate Affairs & Governance is responsible for the overseeing of the implementation of this policy reporting progress back to the Director of Nursing, Performance and Quality.

2.5 The Deputy Director of Corporate Affairs & Governance is responsible for ensuring there are appropriate systems and controls in place to facilitate this adherence to this policy.

2.6 The Head of Integrated Governance is responsible for the review and amendment of the policy.

2.7 The Integrated Governance Manager is responsible for ensure procedures are in place to support this policy.

2.8 The Clinical Effectiveness Team are responsible for the monitoring of its implementation within the Trust.

2.9 All medical practitioners of the East Cheshire NHS Trust, if introducing a “new interventional procedure” as defined by HSC 2003/011 issued on the 13th November 2003 will which he/she has not used before, or only used outside the NHS, must obtain approval from the Trust’s Safety, Quality and Standards Committee.

2.10 The Trust's Safety, Quality and Standards Committee will have responsibility for approving “new interventional procedure” as defined by HSC 2003/011.
3.0 Planning and implementation

3.1 Summary
All medical practitioners planning to undertake a new interventional procedure, or an interventional procedure which they have only used outside the NHS, are required to seek approval from the Trust's Safety, Quality and Standards (SQS) Committee before doing so. If the procedure is the subject of the National Institute of Clinical Excellence (NICE) guidance the Committee will consider whether its proposed use complies with the guidance before granting approval. If the procedure is not listed on the NICE website the Chair of the Trust's Safety, Quality and Standards Committee will notify the procedure to the Interventional Procedures Programme at NICE. In a case where the procedure has to be used in an emergency the procedure must be notified to the Trust's Safety, Quality and Standards Committee within 72 hours.

3.2 Definition
An Interventional Procedure is one used for diagnosis or treatment that involves incision, puncture, entry into a body cavity, electromagnetic or acoustic energy.

An interventional procedure should be considered new if a doctor, no longer in a training post, is using it for the first time in his or her NHS clinical practice.

4. Process

4.1 Any doctor considering use of an interventional procedure new to the Trust, within the Trust, which he/she has not used before, or only used outside the NHS, must obtain approval from the Trust's Safety, Quality and Standards Committee. (Appendix 1)

4.2 Where the procedure is not listed on the NICE website as issued (www.nice.org.uk/ip) the Chair of the Committee will notify the procedure to NICE via the website.

4.3 If the procedure has already been assessed by NICE, the committee will consider if the proposed use complies with the guidance, before granting approval.

4.4 Where no NICE guidance on the procedure is available the committee will only approve its use if:

- The doctor has met externally set standards of training
- Patients are informed during the consent process of the special status of the procedure and the lack of experience of its use. (This must be clearly recorded). The uncertainty of the safety and efficacy, and anticipated benefits and possible adverse effects of the procedure must be detailed to the patient with information about alternative procedures including that of no treatment.
- Clinical audit arrangements are comprehensive and will provide data on clinical outcomes enabling review of the continued use of the procedure.
- A Trust training programme is in place which meets the criterion of the NHSLA standard 5.2.6.

4.5 In a clinical emergency, where no other treatment options exist, a doctor may need to use a new procedure so as not to place a patient at serious risk. Information about this must be passed to the Trust's Safety, Quality and Standards Committee.
within 72 hours. The committee will then consider any future use of the procedure via the approval process as set out above.

4.6 If an adverse incident occurs in association with a new interventional procedure, this must be reported to the National Patient Safety Agency.

4.7 For any new interventional procedure which is notified to NICE, the doctor who wishes to undertake the procedure will supply information requested by NICE on every patient undergoing the procedure to facilitate their speedy assessment on its safety and efficacy. (Further details of how the NICE Interventional Procedures Programme works is cited in section 4 of Health Service Circular 2003/011).

4.7 Exceptions
The only exception to the above process is when a procedure is being used within a protocol approved by a Research Ethics Committee, as patients are protected by the REC’s analysis of the protocol.

5.0 Measuring performance
Key performance indicator identified relating to this policy is as follows:
All medical practitioners of the East Cheshire NHS Trust, if introducing a “new interventional procedure” as defined by HSC 2003/011 issued on the 13th November 2003 which he/she has not used before, or only used outside the NHS, must obtain approval from the Trust’s Safety, Quality and Standards Committee.

6.0 Audit
This policy will be audited in line with the KPI’s identified in section 5.0 on an annual basis by the Clinical Effectiveness Department and reported to the CARE Group. Any action plans developed from this audit will be agreed by the CARE Group with a monthly review of progress.

7.0 Review
This policy will be reviewed on a three yearly basis, or earlier if HSC 2003/011 is amended, by the Head of Integrated Governance.

8.0 Bibliography:
(link checked 08/04/2016)
Appendix 1
NEW CLINICAL INTERVENTIONAL PROCEDURES APPLICATION FORM

PART A (to be completed by requesting Consultant)

Consultant/Service Line ____________________________________________

Name of procedure ______________________________________________

________________________________________________________________

Description _____________________________________________________

________________________________________________________________

New Procedure listed on NICE website Yes / No / Not known

Estimated no. of patients to be treated/annum ______________________

Current available procedure(s) _____________________________________

________________________________________________________________

Impact on other services (eg; Path Lab, Theatres, Wards)

________________________________________________________________

Claimed advantage(s) over existing procedure(s) for same indication(s)

________________________________________________________________

________________________________________________________________

Evidence for claimed benefits (please attach copies of papers or quote references)

________________________________________________________________

________________________________________________________________

________________________________________________________________
Cost implications for Trust:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

PART B (approval by Service Line SQS Committee on grounds of clinical effectiveness)

Conditions of approval (ie; review period, etc)

________________________________________________________________________

________________________________________________________________________

Signature ____________________________________________
(Chair of Service Line SQS Committee)

Date ____________________________________________

This completed form must be returned to your Clinical Director / Associate Director for submission to the Trust’s SQS Committee, and a copy to the Clinical Effectiveness Department, New Alderley House.
New Clinical Interventional Procedures Policy

May 2016 Fiona Smith

Equality Analysis (Impact assessment)

Please START this assessment BEFORE writing your policy, procedure, proposal, strategy or service so that you can identify any adverse impacts and include action to mitigate these in your finished policy, procedure, proposal, strategy or service. Use it to help you develop fair and equal services.

Eg. If there is an impact on Deaf people, then include in the policy how Deaf people will have equal access.

1. What is being assessed?

New Clinical Interventional Procedures Policy

Details of person responsible for completing the assessment:

- Pam Laird
- Integrated Governance Manager
- Corporate Affairs & Governance

State main purpose or aim of the policy, procedure, proposal, strategy or service:

(usually the first paragraph of what you are writing. Also include details of legislation, guidance, regulations etc which have shaped or informed the document)

The purpose of this policy is to ensure compliance by medical practitioners of the Trust with HSC 2003/011 “The Interventional Procedures Programme” issued on the 13th November 2003.

All medical practitioners planning to undertake a new interventional procedure, or an interventional procedure which they have only used outside the NHS, are required to seek approval from the Trust’s Safety, Quality and Standards (SQS) Committee before doing so. If the procedure is the subject of NICE guidance the Committee will consider whether its proposed use complies with the guidance before granting approval.

2. Consideration of Data and Research

To carry out the equality analysis you will need to consider information about the people who use the service and the staff that provide it. Think about the information below – how does this apply to your policy, procedure, proposal, strategy or service

2.1 Give details of RELEVANT information available that gives you an understanding of who will be affected by this document

Cheshire East (CE) covers Eastern Cheshire CCG and South Cheshire CCG. Cheshire West & Chester (CWAC) covers Vale Royal CCG and Cheshire West CCG. In 2011, 370,100 people resided in CE and 329,608 people resided in CWAC.

Age:

- East Cheshire and South Cheshire CCG’s serve a predominantly older population than the national average, with 19.3% aged over 65 (71,400 people) and 2.6% aged over 85 (9,700 people).
- Vale Royal CCGs registered population in general has a younger age profile compared to the CWAC average, with 14% aged over 65 (14,561 people) and 2% aged over 85 (2,111 people).

Since the 2001 census the number of over 65s has increased by 26% compared with 20% nationally. The number of over 85s has increased by 35% compared with 24% nationally.

Race:

- In 2011, 93.6% of CE residents, and 94.7% of CWAC residents were White British
- 5.1% of CE residents, and 4.9% of CWAC residents were born outside the UK – Poland and India being the most common
- 3% of CE households have members for whom English is not the main language (11,103 people) and 1.2% of CWAC households have no people for whom English is their main language.

Gender:

- In 2011, c. 49% of the population in both CE and CWAC were male and 51% female. For CE, the assumption from national figures is that 20 per 100,000 are likely to be transgender and for CWAC 1,500 transgender people will be living in the CWAC area.

Disability:

- In 2011, 7.9% of the population in CE and 8.7% in CWAC had a long term health problem or disability
- In CE, there are c.4500 people aged 65+ with dementia, and c.1430 aged 65+ with dementia in CWAC. 1 in 20 people over 65 has a form of dementia
- Over 10 million (c. 1 in 6) people in the UK have a degree of hearing impairment or deafness.
- C. 2 million people in the UK have visual impairment, of these around 365,000 are registered as blind or partially sighted.
- In CE, it is estimated that around 7000 people have learning disabilities and 6500 people in CWAC.
- Mental health – 1 in 4 will have mental health problems at some time in their lives.

Sexual Orientation:

- CE - In 2011, the lesbian, gay, bisexual and transgender (LGBT) population in CE was estimated at18,700, based on assumptions that 5-7% of the population are likely to be lesbian, gay or bisexual and 20 per 100,000 are likely to be transgender (The Lesbian & Gay Foundation).
• CWAC - In 2011, the LGBT population in CWAC is unknown, but in 2010 there were c. 20,000 LGB people in the area and as many as 1,500 transgender people residing in CWAC.

Religion/Belief:
The proportion of CE people classing themselves as Christian has fallen from 80.3% in 2001 to 68.9% in 2011 and in CWAC a similar picture from 80.7% to 70.1%, the proportion saying they had no religion doubled in both areas from around 11%-22%.
- Christian: 68.9% of Cheshire East and 70.1% of Cheshire West & Chester
- Sikh: 0.07% of Cheshire East and 0.1% of Cheshire West & Chester
- Buddhist: 0.24% of Cheshire East and 0.2% of Cheshire West & Chester
- Hindu: 0.36% of Cheshire East and 0.2% of Cheshire West & Chester
- Jewish: 0.16% of Cheshire East and 0.1% of Cheshire West & Chester
- Muslim: 0.66% of Cheshire East and 0.5% of Cheshire West & Chester
- Other: 0.29% of Cheshire East and 0.3% of Cheshire West & Chester
- None: 22.69% of Cheshire East and 22.0% of Cheshire West & Chester
- Not stated: 6.66% of Cheshire East and 6.5% of Cheshire West & Chester

Carers: In 2011, nearly 11% (40,000) of the population in CE are unpaid carers and just over 11% (37,000) of the population in CWAC.

2.2 Evidence of complaints on grounds of discrimination: (Are there any complaints or concerns raised either from patients or staff (grievance) relating to the policy, procedure, proposal, strategy or service or its effects on different groups?)

No

2.3 Does the information gathered from 2.1 – 2.3 indicate any negative impact as a result of this document?

No

3. Assessment of Impact

Now that you have looked at the purpose, etc. of the policy, procedure, proposal, strategy or service (part 1) and looked at the data and research you have (part 2), this section asks you to assess the impact of the policy, procedure, proposal, strategy or service on each of the strands listed below.

RACE:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, racial groups differently?  Yes  No  ✔

Explain your response:
All racial groups will be treated the same with regard to being a potential candidate for a new clinical intervention. Re 3.4 bullet point 2 – staff must follow the trust interpretation policy to ensure patients understand the risks and benefits and can engage in a meaningful way in the consent process.

GENDER (INCLUDING TRANSGENDER):
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, different gender groups differently?  Yes  No  ✔

Explain your response:
All potential candidates, regardless of gender group, will be treated the same

DISABILITY
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, disabled people differently?  Yes  No  ✔

Explain your response:
Re 3.4 bullet point 2 – staff must follow the trust interpretation policy to ensure patients understand the risks and benefits and can engage in a meaningful way in the consent process. For patients assessed as lacking capacity, best interests will need to be implemented.

AGE:
From the evidence available does the policy, procedure, proposal, strategy or service, affect, or have the potential to affect, age groups differently?  Yes  No  ✔

Explain your response:
All potential candidates, regardless of age, will be treated the same

LESBIAN, GAY, BISEXUAL:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, lesbian, gay or bisexual groups differently?  Yes  No  ✔

Explain your response:
All potential candidates, regardless of sexuality, will be treated the same, with partners involved in discussion in the same way as heterosexual partners.

RELIGION/BELIEF:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, religious belief groups differently?  Yes  No  ✔

Explain your response:
If there are any drugs used in the procedure /intervention, staff will check with pharmacy for any substances which may conflict with religious belief, i.e. Muslim patients and porcine products.
CARERS:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, carers differently? Yes ☑️ No ☐

Explain your response:
If a candidate has caring responsibilities, staff will be mindful of this ensuring that the implications of the intervention are fully understood in the light of the patient’s ongoing commitments.

OTHER: EG Pregnant women, people in civil partnerships, human rights issues.
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect any other groups differently? Yes ☐️ No ☑️

Explain your response:
If a potential candidate is pregnant, consideration will be given to the health risk to the unborn child of any procedure.

4. Safeguarding Assessment - CHILDREN
a. Is there a direct or indirect impact upon children? Yes ☑️ No ☐

b. If yes please describe the nature and level of the impact (consideration to be given to all children; children in a specific group or area, or individual children. As well as consideration of impact now or in the future; competing / conflicting impact between different groups of children and young people:
If a new clinical interventional procedure was being carried out on a child the same permissions would need to be sought in relation to approval and in addition standard consent requested from parent or guardian prior to any procedure being undertaken. For further guidance on “The Interventional Procedures Programme” please refer to the NICE website www.nice.org.uk.

c. If no please describe why there is considered to be no impact / significant impact on children

5. Relevant consultation
Having identified key groups, how have you consulted with them to find out their views and that the policy, procedure, proposal, strategy or service will affect them in the way that you intend? Have you spoken to staff groups, charities, national organisations etc?

CARE (Clinical Audit Research and Effectiveness) Group

6. Date completed: 28.4.16 Review Date: April 2019

7. Any actions identified: Have you identified any work which you will need to do in the future to ensure that the document has no adverse impact?

<table>
<thead>
<tr>
<th>Action</th>
<th>Lead</th>
<th>Date to be Achieved</th>
</tr>
</thead>
</table>

8. Approval – At this point, you should forward the template to the Trust Equality and Diversity Lead lynbailey@nhs.net

Approved by Trust Equality and Diversity Lead:

Date: 28.4.16