CAUTION: You must refer to the intranet for the most recent version of this policy.

Policy for handling and instilling intravesical treatments to urology patients with superficial bladder cancer

<table>
<thead>
<tr>
<th>SharePoint Location</th>
<th>Clinical Policies and Guidelines</th>
</tr>
</thead>
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<tr>
<td>SharePoint Index Directory</td>
<td>Surgery</td>
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<td>Urology</td>
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<td>Intravesical treatments, Bladder cancer, Mitomycin, BCG</td>
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<tr>
<td>Endorsing Body</td>
<td>Urology CMT</td>
</tr>
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<td>Endorsement Date</td>
<td>May 2010</td>
</tr>
<tr>
<td>Review Date</td>
<td>May 2011</td>
</tr>
<tr>
<td>Lead author and designation</td>
<td>Sue Thompson, Urology Nurse Practitioner Chris Dawson, Clinical Lead Urology CMT</td>
</tr>
<tr>
<td>Review led by</td>
<td>Urology CMT</td>
</tr>
</tbody>
</table>
Policy for handling and instilling intravesical treatments to urology patients with superficial bladder cancer

Key Points

This policy has been produced to ensure that the above procedure is performed safely and to a high standard throughout the Trust. As more ward nurses and specialist practitioners are now being trained to perform this procedure it was felt that the trust should update its own policy and procedure document.

The purpose of this policy is to ensure that all practitioners are able to perform the procedure safely and to provide an assessment document. The intention is to prevent the occurrence of inconsistent practice of clinical staff that prepare, handle, instill and dispose of intravesical treatments (Mitomycin C and BCG) in the management of superficial bladder cancer.

This policy has been assessed using an Equality Impact Assessment screening template and has no adverse impact on any particular group, sex, ethnicity, religion, gender or disability. As a result it is considered that a full Equality Impact Assessment is not necessary."
CAUTION: You must refer to the intranet for the most recent version of this policy.

Index page:

Procedure for handling and instilling intravesical treatments:

1. Introduction and general warning
2. List of equipment needed for the procedure
3. Action for procedure with supporting rational
   3.1 Preparation
   3.2 Reconstituting
   3.3 Administration
   3.4 Post administration
4. Instructions for accidents or spillages
5. Competency documents:
   5.1 Competency 1
   5.2 Competency 2
   5.3 Competency 2
   5.4 Practice sessions record sheet
   5.5 Statement of competence

Appendix 1  Equality Impact Assessment form
**CAUTION:** You must refer to the intranet for the most recent version of this policy.

**Procedure for handling and instilling intravesical treatments in urology patients with superficial bladder cancer**

1. **Introduction**
   Intravesical therapy is used in the treatment of patients with bladder cancer:

   1. As prophylaxis to reduce the rate of recurrence and progression, with the aim of increasing the disease free interval and possibly delay progression to muscle invasion
   2. As treatment where Trans urethral resection alone is inadequate
   3. As a treatment to eradicate residual transitional cell carcinoma, if patients have frequent superficial recurrence

   Cytotoxic drugs contain mutagenic, carcinogenic and teratogenic properties. These may be hazardous to those preparing and using them.

2. **Equipment**

<table>
<thead>
<tr>
<th>Protective paper sheet and paper towel for bed/couch</th>
<th>Instillagel (if required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trolley prepared for an aseptic procedure</td>
<td>Dressing pack and cleaning agent</td>
</tr>
<tr>
<td>Orange disposable bags x2 (one inside the other)</td>
<td>Timer (if available) or patients watch/clock</td>
</tr>
<tr>
<td>Cytotoxic (purple lid) yellow sharps bin</td>
<td>Spillage pack for Mitomycin and hypochlorite solution to neutralize any BCG spillage</td>
</tr>
<tr>
<td>Cytotoxic tape</td>
<td>Sterile syringe (if removal of catheter necessary)</td>
</tr>
<tr>
<td>Nitrile gloves</td>
<td>50ml Luer lock syringe (Mito only)</td>
</tr>
<tr>
<td>Goggles</td>
<td>Saline to reconstitute BCG</td>
</tr>
<tr>
<td>Mask for reconstituting</td>
<td>Water to reconstitute MMC</td>
</tr>
<tr>
<td>Disposable apron</td>
<td>Reconstitution giving sets</td>
</tr>
<tr>
<td>Coloplast Speedicath size 10 unless patient already catheterized or has specific requirements</td>
<td>Hospital pyjamas/gown/pts own clothes – Patient’s choice</td>
</tr>
</tbody>
</table>

The prescription sheet and drugs should be checked against the prescription with another member of qualified nursing or medical staff.
3. **Action** | **Rationale**
---|---
### 3.1 Preparation:
1.a Explain procedure to the patient and ensure they have received an information leaflet  
To ensure patient has good understanding of the procedure and obtain their verbal consent. To ensure that the patient has reference material
1.b Ensure 14 days have elapsed since TURBT (first BCG treatment only)  
To avoid BCG entering the blood stream at the site of the TUR and causing a systemic reaction
2. Patient should be advised to limit their fluid intake for approx 4 hours prior to installation  
To avoid dilution of cytotoxic drug after installation.  
To avoid patient discomfort when retaining drug for 1-2 hours as a result of bladder filling
3. Check there have been no side effects or problems since the last treatment:  
- ↑ Temperature  
- Cystitis  
- Rash  
- UTI (perform urinalysis each week if outpatient)  
To ensure patient suitable to receive treatment. Adverse effects need to be discussed with doctor, possible need to delay and rearrange treatment as required
4. Inco sheets placed on the bed/couch  
To avoid unnecessary disposal of linen and mattress should spillage occur
5.a Patient to wear hospital pyjamas/theatre gown during the procedure (in-patients)  
To avoid damage to patients clothing should spillage occur
b Patient to remove lower clothing (out-patients)
6. Check all details of the drug with prescription chart, hospital number on case notes and by asking the patient their name and date of birth with another member of staff  
To ensure correct identification of patient and prescribed drug
### 3.2 Reconstituting general
Put on mask, goggles, apron and nitrile gloves and assemble all equipment aseptically, in  
To prevent infection, reduce the risk of drug contamination and to protect staff handling the drugs
CAUTION: You must refer to the intranet for the most recent version of this policy.

designated area for reconstituting (tray and chemo mat)

3.2.1 Reconstituting BCG
1. Receive BCG and saline giving set from pharmacy and open outer bags
2. Close both clips on saline giving set and attach BCG vial to it (only connects one way)  
   To ensure vial is held in place by the clamp
3. Open the clip between saline and BCG and snap the internal valve and gently squeeze some saline into dry powder in vial. Re-clip tube.
4. Gently swirl  
   To allow the saline to fully mix with the powder
5. Release clip and draw back into the saline bag
6. Close the clip to the vial and connect to catheter with catheter tip end  
   Allowing reconstituted BCG to be injected into the catheter

3.2.2 Reconstituting MMC
1. Draw up 40 mls of water into the luer lock syringe using the air inlet device
2. Close all clips on giving set and push the giving set nozzle onto the vial of MMC  
   To ensure vial is held in place by a clamp
3. Connect the syringe to the giving set at white end and open the 2 white clips and gently inject 10mls into vial of powder. Close clips
4. Gently swirl  
   To allow the water to fully mix with the powder
5. Open white clips and draw back into the syringe and close clips again  
   To ensure drug fully mixed
6. Attach to catheter using catheter connection provided  
   To allow reconstituted MMC to be injected into the catheter
CAUTION: You must refer to the intranet for the most recent version of this policy.

3.3 Administration:

1. Wash hands
   To prevent cross infection

2. Place inco sheet under penis or between thighs of the patient
   To protect skin in case of any involuntary leakage of cytotoxic drug during the procedure

3. Assemble all equipment aseptically and ensure goggles are on
   To prevent infection and to protect staff handling the drugs

4. a. Catheterize patient (if not already in situ) in accordance with Trust policy, using a speedicath/patient specific catheter, and drain bladder into clean receptacle.
   To provide route for installation. To ensure empty bladder prior to installation of drug, to avoid dilution of drug and increase comfort and tolerance

   b. If catheter is already in place, using aseptic technique, place sterile towel under the catheter and disconnect the drainage bag and drain excess urine into receptacle

5. Check instillation system is clamped off and connect to catheter
   To avoid accidental spillage onto staff or patient. To facilitate drug installation

6. Release clip when sure of a secure connection to catheter.
   Gently squeeze the syringe or instillation system to administer drug. DO NOT use force
   To avoid spillage of drug prior to installation. Rapid infusion is uncomfortable for the patient, especially if the bladder is small or scarred by previous treatment or disease. It may cause bladder spasm resulting in rejection of the drug

7. Close all clips once drug has been installed
   Prevent any leakage onto patient or staff

8a In-patients
   If catheter to remain in situ and once the correct volume has been instilled apply closed flip/flow valve (ensuring catheter is clamped whilst disconnecting giving set)
   Otherwise deflate balloon and remove catheter with giving set still attached. Immediately dispose in
CAUTION: You must refer to the intranet for the most recent version of this policy.

8b Outpatients
Remove catheter whilst still attached to giving set and dispose of equipment into cytotoxic sharps bin

The catheter is not required for continued urinary drainage. The risk of infection is greater if left insitu.

3.4 Post administration:

Mitomycin (Chemotherapy)

1. Ask patient if they wish to alternate position from front to back and side to side at 15 minute intervals for 1 hour, commencing with the prone (tummy) position, otherwise they can simply mobilize

To ensure that all inner surfaces of the bladder are coated with the drug.
To prevent discomfort from lying on a full bladder
No evidence to support rotation, but patients choice

2a. Inpatients
Give patient nurse call bell and advise of time of completion
Offer use of a timer (if available)

To ensure patient has contact with the nurse and knows when treatment is to be completed

2b. Outpatients
Advise patient of what time to empty bladder

To ensure patient is fully aware of treatment completion time

BCG (Immunotherapy)

3. Remove catheter and ask patient to hold BCG in their bladder for 2 hours before voiding (if unable to tolerate for 2 hours they must go when need to urinate to reduce risk of contamination)

To decrease the risk of infection and increase ability to retain BCG without spillage

4. Patient encouraged to mobilize for first treatment in outpatients but can lie down and alternate position from front to back and side to side at 15 minute intervals once at home in subsequent weeks, commencing with the prone (tummy) position.

To ensure that all inner surfaces of the bladder are coated with the drug.
To prevent discomfort from lying on a full bladder
No evidence to support rotation, but patients choice
### General

1. **Place giving set and catheter into a cytotoxic sharps bin, close and seal with cytotoxic tape. Place in designated area for disposal**
   - To avoid spillage and to ensure correct disposal of cytotoxic drug

2. **Any leakage onto bed linen and all disposal equipment to be placed into double orange bags. Bags to be sealed with cytotoxic tape and placed in designated area for disposal**
   - To ensure correct disposal of cytotoxic waste

3. **If there is any leakage on the patients skin, the spillage policy (below) should be followed**
   - To avoid excoriation of the skin

4. **Inform medical staff of any leakage and complete clinical incident form**
   - To ensure medical staff aware should further action be required

5. **Complete intravesical treatment chart and record in medical notes (include batch number and expiry date)**
   - To ensure correct documentation and track ability of drugs

6. **Check patient comfortable and confirm next appointment. Patient to have advice information leaflet and contact telephone numbers before first visit (see information leaflet)**
   - To ensure patient satisfied. To improve understanding of possible side effects and required action
   - To reduce anxiety experienced by the patient

7. **Outpatients**
   - If last treatment, complete a GP discharge letter and give a copy to the patient
   - To ensure Primary Care Team are kept informed

### 4. Accidents and Spillages
**CAUTION:** You must refer to the intranet for the most recent version of this policy.

Any spillage or leakage to be dealt with whilst wearing protective clothing by the member of staff carrying out the procedure (and not delegated to cleaning staff).

**Mitomycin:**

**Work surfaces:** Spillages should be mopped with disposable cloths and then washed with copious amounts of cold water. Porous apparatus should be condemned.

**Skin:** Areas to be washed with 8.4% sodium bicarbonate and then with copious amounts of cold water. Avoid hand creams. Inform doctor and occupational health if a rash appears.

**Eyes:** Irrigate immediately with eye solution and then sodium chloride 0.9% eye wash and seek medical attention. Inform occupational health.

**Clothing Contamination:** If any clothing has been contaminated, it should be removed as soon as possible. Placed into two yellow bags and sealed with cytotoxic tape and sent for incineration.

**BCG:**

All exposure should be reported to occupational health. A health test is recommended at the time of the incident and six weeks later and followed up by a doctor if required.

**Inhalation:** Remove to be in the fresh air. Seek medical evaluation. Advice occupational health.

**Skin contact:** Wash thoroughly with soap and water, clean any open sores or finger lacerations with alcohol. Inform medical staff and occupational health.

**Eyes:** Flush with copious amounts of water for 15 minutes. Inform medical staff and occupational health.

**Work surfaces:** Allow disposable towels to soak with tuberculocidal disinfectant (Hyperchloride solution) on affected area. Dispose of equipment if permeable.

**Clothing Contamination:** If any clothing has been contaminated, it should be removed as soon as possible. Placed into two yellow bags and sealed with cytotoxic tape and sent for incineration.
Appropriate documentation should be made if any of the above incidents Occur.
It is essential all incidents involving accidental spillage be reported. An accident/incident report must be filled in recording all details and then sent through the appropriate channels (as Trust policy).

5. Handling and Instilling Intravesical Treatments

5.1 Competency 1

The nurse will be able to:

1. Identify ethical, legal and professional implications of this policy
2. Describe regularly used cytotoxic drugs
   - drug dosages
   - drug action
   - drug side effects
   - contraindications
3. Describe current health of patient
4. Identify interventions, which may prevent side effects of cytotoxic agents
5. Describe action in event of
   - spillage
   - leakage
   - skin contact
   - eye contact
6. Identify the need for correct documentation of actions
7. Demonstrate awareness of reconstitution of cytotoxic agents
8. State resources available for consultation about administration of cytotoxic agents
9. Describe application of the Scope of Professional Practice (1992)
5.2 Handling and Instilling Intravesical Treatments

Competency 2

The nurse will be able to:  

1. Collect all the required equipment       
2. Prepare the required equipment appropriately
3. Reconstituted drugs (MMC & BCG) appropriately
4. Check the orders regarding cytotoxic agent and question as appropriate
5. Practised procedure in safe manner, according to the guidelines
6. Ensure all equipment is disposed safely according to Trust guidelines
7. Demonstrate ability to document actions appropriately
8. Administer cytotoxic therapy as indicated in cytotoxic procedure
9. Administer cytotoxic agent following:
   - one observation of procedure
   - one supervised practice of procedure
   - one assessed procedure

PASS      FAIL
5.3 Handling and Instilling Intravesical Treatments

Competency 3

The nurse will be able to:

1. Check drug to be administered with second individual and complete checklist in accordance with hospital policy.  
   - PASS  FAIL

2. Prepare the patient with regard to:
   - information
   - consent

3. Assess the patient’s general condition prior to administration of cytotoxic agent.

4. Ensure the patient understands the side effects of cytotoxic agents.

5. Check and verbally confirm the patient’s identity prior to administration.

6. Following administration observe:
   - patient’s comfort
   - fluid balance monitored if trial without catheter
   - safe disposal of all equipment

7. For day case patients complete GP correspondence accurately.
   - Understand the nurse’s professional accountability in doing so.

8. Documents action in the patients’ intravesical treatment chart and their medical notes.
5.4 Handling and Instilling Intravesical Treatments

Practice sessions

The nurse/practitioner must be supervised whilst preparing the patient and environment for cytotoxic agents and the form should be signed only if the nurse/practitioner is deemed a competent practitioner. The nurse/practitioner must have already been successfully assessed using the protocol.

NAME: ____________________________

<table>
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<tr>
<th>DATE</th>
<th>SUPERVISOR’S SIGNATURE</th>
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<tr>
<td>DEMONSTRATION</td>
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<tr>
<td>SUPERVISED PRACTICE</td>
<td></td>
</tr>
<tr>
<td>ASSESSED PRACTICE</td>
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</tbody>
</table>

When the nurse/practitioner has successfully completed an observation, a supervised practice and an assessed practice he/she will be able to administer intravesical cytotoxic agents unsupervised until the agreed review date.
5.5

Handling and Instilling Intravesical Treatments

Statement of competence

This statement should only be signed when the nurse/practitioner and supervisor are confident that the former has attained the learning outcomes.

1. The practitioner has successfully completed the competencies.  
   Yes / No

2. The practitioner has successfully performed the procedures under supervision.  
   Yes / No

3. The practitioner and supervisor have agreed and recorded a review date.  
   Yes / No

Review date: __________________________

Practitioner: __________________________  Supervisor: __________________________

Signature: __________________________  Signature: __________________________

Print name: __________________________  Print name: __________________________

Date: __________________________  Date: __________________________

One copy of this statement should be kept in the staff file, and a copy given to the practitioner.
**CAUTION:** You must refer to the intranet for the most recent version of this policy.

Endorsement
This policy will be approved and endorsed by the Urology CMT

Distribution
The policy will be available on SharePoint and distributed Trust wide

Implementation and monitoring

National standards for policy development and implementation are set by the NHS Litigation Authority (NHSLA), National Patient Safety Association (NPSA) and Care Quality Commission (CQC).

Review of the document will be undertaken by the development leads or other interested parties when review deadline is imminent, or before if changes in practice make it necessary to do so.

The policy will be monitored through the audit process to ensure it is adhered to in practice by the members of staff performing the procedure.

Please see attached monitoring table which shows how the policy will be monitored.

This policy has been assessed using an Equality Impact Assessment screening template and has no adverse impact on any particular group, sex, ethnicity, religion, gender or disability. As a result it is considered that a full Equality Impact Assessment is not necessary. (see appendix 1)

References


European Association of Urology, 2008, Guidelines on TaT1 (non-muscle invasive) Bladder Cancer

Summary and Audit Trail

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</tr>
</tbody>
</table>

| Tick the appropriate boxes below to indicate where and to whom the policy applies: |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Trust and Shared Care | Trustwide | CBU | Department | x |
| Multidisciplinary | x | Medical Staff | x | Nursing / Midwifery | x |
| x | x | Allied Health Professionals |

**Reason for Development:** to ensure consistent practice when performing bladder treatment to patients by all staff performing the procedure

<table>
<thead>
<tr>
<th>Development Lead(s):</th>
<th>Sue Thompson Urology Nurse Practitioner</th>
</tr>
</thead>
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<tr>
<td><strong>Tel. Number:</strong></td>
<td>X8756</td>
</tr>
<tr>
<td><strong>Email Address:</strong></td>
<td><a href="mailto:Susan.thompson@pbh-tr.nhs.co.uk">Susan.thompson@pbh-tr.nhs.co.uk</a></td>
</tr>
</tbody>
</table>

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<th>Key sources of evidence</th>
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<tbody>
<tr>
<td>Sue Thompson</td>
<td></td>
</tr>
<tr>
<td>Sue Pilcher</td>
<td></td>
</tr>
<tr>
<td>Urology Consultants</td>
<td></td>
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</tbody>
</table>

**Consultation Process**

**Please list key Staff Members and Groups/Committees involved in the Consultation Process:**

Urology CMT and Clinical Nurse Specialists

**Please identify committee(s) which will approve the policy:**

Urology CMT
## Compliance Monitoring

**Policy Title:** Policy for handling and Instilling Intravesical Treatments to Urology Patients with Superficial Bladder Cancer  
**Author:** Sue Thompson

<table>
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<th>Process in the policy to be monitored</th>
<th>How will compliance with the outlined process be monitored?</th>
<th>Frequency</th>
<th>By who?</th>
<th>If compliance gaps have been identified, who is responsible for creating an action plan, and ensuring implementation of required changes?</th>
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<tr>
<td>Safe handling, mixing and administration of intravesical treatments for urology patients with superficial bladder cancer as stated in policy</td>
<td>Clinical audit and peer review</td>
<td>Ongoing but at least yearly</td>
<td>Urology Clinical/Specialist Nurse Practitioners</td>
<td>Urology CMT</td>
</tr>
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*CAUTION: You must refer to the intranet for the most recent version of this policy.*
APPENDIX 1

**STAGE ONE : Equality Impact Assessment (EqIA) Screening form**

**Assessing Functions/Policies for Relevance**

Blue boxes are to be filled in
Yellow boxes - Click the box to select from the drop down list

| Name of function/service/strategy/policy/project (activity) to be assessed: | Policy for the handling and instilling intravesical treatments to urology patients with superficial bladder cancer |
| Name(s) of those completing this EqIA Screening form: | Sue Thompson Urology Nurse Practitioner |
| CBU/Department | Surgery |
| Date | 01-Oct-10 |

| Function/service/strategy/policy/project (activity) aim or purpose: | ensure continuity of care to patients with bladder cancer |
| Is this a new or existing activity? | existing activity |
| What are the intended results of this activity? | staff awareness and patient continuity of care |
CAUTION: You must refer to the intranet for the most recent version of this policy.

How will you measure the outcome of the activity? clinical audit and peer review

Who is intended to benefit from the activity? patients receiving intravesical treatments for superficial bladder cancer

Please identify any internal/external groups who have been consulted regarding this activity: Urology CMT

Use the table below to identify whether the activity could/does have a positive impact, a negative impact or no impact at all on either any or all of the equality groups specified.

<table>
<thead>
<tr>
<th>Age</th>
<th>Disability</th>
<th>Ethnicity/Race</th>
<th>Gender</th>
<th>Religion/Belief</th>
<th>Sexual Orientation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eliminating unlawful or unjustifiable discrimination</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
</tr>
<tr>
<td>Promoting equality of opportunity</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
</tr>
<tr>
<td>Promoting positive attitudes and good community relations</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
</tr>
<tr>
<td>Eliminating harassment or victimization</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
</tr>
<tr>
<td>Encourage involvement and participation</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
<td>neutral</td>
</tr>
</tbody>
</table>
CAUTION: You must refer to the intranet for the most recent version of this policy.

Eliminating health inequalities

| Neutral | Neutral | Neutral | Neutral | Neutral | Neutral |

If there is either a Positive (Disability group exempted) or a Negative impact you must consider completing the Stage Two - Full Equality Impact Assessment form to address or remove any significant potential/actual impact.

Decision to proceed (please select):

If you have selected "Yes, a full EqIA is required", please identify when the Full EqIA will be completed. Date

Reason for decision to proceed or not to full EqIA

| Not necessary to proceed to full EqIA |

Executive Director/General Manager - I confirm that I have been briefed and agree with the results of this EqIA.

Name: Chris Dawson

Job Title: Clinical Lead for Urology Oncology and CMT

Date: Oct-10

Please note the following:

It is essential that this EqIA screening form is discussed by your management team and remains readily available for inspection. A copy should also be forwarded to the Communications team for publication on the Trust's internet site.