NEWCASTLE, NORTH TYNESIDE, NORTHUMBERLAND AND GATESHEAD GUIDELINES FOR MANAGEMENT OF ERECTILE DYSFUNCTION IN ADULTS ≥ 18 YEARS

September 2015
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INTRODUCTION

This guidance is intended to inform management of erectile dysfunction in primary care and has been developed as a consensus between representatives from primary and secondary care with reference to national guidelines, including from NICE as appropriate. The guidelines are intended to guide clinical management, but every patient should be assessed and managed individually.

These guidelines are intended for all clinicians in primary care in the Newcastle, North Tyneside, Northumberland and Gateshead areas involved in managing patients with erectile dysfunction. This is the first iteration of these guidelines and any gaps should be identified for inclusion when the guideline is reviewed. These guidelines are not intended to provide a comprehensive overview of ED, but to inform decision making during a busy GP surgery.

Reference is made to drugs which are, and are not, available on the North of Tyne formulary. Some drugs are only available on a private prescription basis (unless exempt under schedule 2). This has been the case ever since the Department of Health restricted NHS prescribing of phosphodiesterase inhibitors in 1999 when they were first introduced. With effect from August 1st 2014 these restrictions have been relaxed for generic sildenafil, but the other drugs are available for the restricted group of patients in accordance with Department of Health regulations or on private prescriptions for patients not covered by the regulations and need to be in line with the local formulary. It is important that different options should be available, but the cost should be made clear to patients.

Please note that vacuum erection devices only need to be replaced when there is mechanical failure.

How to use the guidelines

The BNF and the North of Tyne /Gateshead Formulary should be referred to as appropriate.

Referrals

When referral to a secondary care urology clinic is recommended in the guideline, referral for patients to be seen at a local outreach clinic may be preferred. It is anticipated that clinicians in localities where such clinics are available will be aware of them, but further information can be obtained from Newcastle Urology at the Freeman Hospital.
Guidelines for the investigation and management of men with erectile dysfunction

**History**
- medical, sexual, psychosocial
- Illicit drugs, anabolic steroids
- Smoking, alcohol
- Consider iatrogenic causes e.g. drugs - see appendix 1
- Ensure complaint is not premature ejaculation

**Examination**
- BP and BMI
- Secondary sexual characteristics
- Abdomen and genitalia - DRE not necessary (unless associated LUTS)
- Lower limb pulses

**Investigations**
- to identify any underlying disease:
  - Blood glucose (ideally fasting), morning testosterone (between 0800-1100 because of circadian variation), lipid profile
  - Calculate CV risk and manage as per local guidelines
  - IIEF questionnaire (see appendix 2)

**Management in primary care**
- for management of patients with underlying health conditions causing ED
- (set out in Schedule 2 to the NHS (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004)

**Lifestyle changes**
- stop smoking, alcohol in moderation, increase exercise, and lose weight (if BMI raised)
- Manage underlying cause - diabetes, hypertension, IHD
- Oral medication with phosphodiesterase inhibitor, assuming no contraindications (see BNF e.g. regular nitrate use, nicorandil, tamsulosin should not be taken within 6 hours of PD5 inhibitor)
  - **FIRST LINE** - generic sildenafil 50mg. If no response to maximum dose (100mg) →
  - **SECOND LINE** - avanafil 100mg (as required with max dose 200mg - on formulary)
  - **THIRD LINE** - tadalafil 10mg as required with max dose 20mg - on formulary

There is an awareness that other PDE5 inhibitors (e.g. vardenafil, once daily tadalafil) are often prescribed on private prescriptions. It is expected this activity is likely to continue, but this guidance refers to NHS prescribing ONLY

**Provide education for using these drugs**
- Delay in onset of action (30 minutes - 2 hours)
- Erotic/sexual stimulation required
- Warn of possible side-effects including headache, flushing (common), visual disturbance, and priapism (very rare) - refer to BNF
- For sildenafil - avoid high fat meals prior to taking the drugs - can delay onset of action

Consider trial of 4 tablets and titrate to maximum dose depending on response
- Move on to next tablet or stop if ineffective at maximum dose on at least 6 out of 8 attempts
- Generally, research evidence indicates for patients in the 40-60 age range, usage will be one treatment per week (4 per month) for most patients treated for erectile dysfunction.
- **NB**: The Prescriber must endorse the prescription with the reference “SLS”.
- If PD5 inhibitors are contraindicated or ineffective, consider trial of topical alprostadil (Vitaros)

**Treatment failure/non-responder**
- as reported by patient?
- Keen to consider further treatment?
- REFER TO SECONDARY CARE (ED services available at NUTH (see below), and via urology at Wansbeck and OE Gateshead)
Referral guidelines for men being referred to NUTH - access to New Croft via referral letter (for Newcastle patients only - block contract) and Urology via Choose and Book (Surgical Andrology)

**Organic aetiology** including CVD (can refer to New Croft or Urology)
**Psychogenic ED**: consider if
- organic cause unlikely
- young man (< 35)
- situational ED
**ED with ‘severe distress’** (with the exception of generic sildenafil - see Appendix 2)
**Need for psychosexual counselling**
- premature ejaculation

Refer to Sexual Health at New Croft Centre

**Organic aetiology** including CVD (can refer to New Croft or Urology)
**Possible Peyronies?**
**Other urological problems**

Refer to Urology at Freeman Hospital

**Treatments offered:**
- Psychosexual counselling
- PDE5 inhibitors, intracavernosal injections (alprostadil)
- Topical alprostadil (Vitaros)
- Vacuum erection device - if successful, GP will be asked to provide prescription

YES

YES

Treatments offered:
- PDE5 inhibitors,
- Intracavernosal injections (alprostadil)
- Topical alprostadil (Vitaros)
- Vacuum erection device - if successful, GP will be asked to provide prescription Penile prosthesis - semi-rigid/inflatable
- Surgery for Peyronies disease

YES

NO

Treatment failure?
Keen to consider prosthesis?
Peyronies disease?

Discharge to GP for ongoing prescribing

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Review date: September 2017
APPENDIX 1

DRUGS that may contribute to ED

<table>
<thead>
<tr>
<th>CLASS</th>
<th>AGENTS</th>
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<tbody>
<tr>
<td>Diuretics</td>
<td>Thiazides</td>
</tr>
<tr>
<td></td>
<td>Spironolactone</td>
</tr>
<tr>
<td>Antihypertensives</td>
<td>Beta-blockers</td>
</tr>
<tr>
<td></td>
<td>Verapamil</td>
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<tr>
<td></td>
<td>Metyldopa</td>
</tr>
<tr>
<td>Cardiac</td>
<td>Digoxin</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>Tricyclics</td>
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<tr>
<td></td>
<td>MAOIs</td>
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<tr>
<td></td>
<td>SSRIs</td>
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<tr>
<td></td>
<td>Lithium</td>
</tr>
<tr>
<td>H2 antagonists</td>
<td>Cimetidine</td>
</tr>
<tr>
<td></td>
<td>Ranitidine</td>
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</table>

APPENDIX 2

Severe distress - the following criteria should be considered:
- Significant disruption to normal social and occupational activities
- Marked effect on mood, behaviour, social and environmental awareness
- Marked effect on interpersonal relationships

With effect from August 1st 2014, the DH has removed the restrictions on generic sildenafil for severe distress and GPs are able to treat these patients in primary care without the need for referral to specialist services.

NB: If there is a lack of success with the first line choice, to access the other PDE5 inhibitors for severe distress will still require referral for initiation as failure on sildenafil could be due to another cause other than non-response.
APPENDIX 3

The IIEF-5 scoring system

<table>
<thead>
<tr>
<th>Over the past 6 months:</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>How do you rate your confidence that you could get and keep an erection?</td>
<td>Very low</td>
<td>Low</td>
<td>Moderate</td>
<td>High</td>
<td>Very high</td>
</tr>
<tr>
<td>When you had erections with sexual stimulation, how often were your erections hard enough for penetration?</td>
<td>Almost never or never</td>
<td>Much less than half the time</td>
<td>About half the time</td>
<td>Much more than half the time</td>
<td>Almost always or always</td>
</tr>
<tr>
<td>During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?</td>
<td>Almost never or never</td>
<td>Much less than half the time</td>
<td>About half the time</td>
<td>Much more than half the time</td>
<td>Almost always or always</td>
</tr>
<tr>
<td>During sexual intercourse, how difficult was it to maintain your erection to the completion of intercourse?</td>
<td>Extremely difficult</td>
<td>Very difficult</td>
<td>Difficult</td>
<td>Slightly difficult</td>
<td>Not difficult</td>
</tr>
<tr>
<td>When you attempted sexual intercourse, how often was satisfactory for you?</td>
<td>Almost never or never</td>
<td>Much less than half the time</td>
<td>About half the time</td>
<td>Much more than half the time</td>
<td>Almost always or always</td>
</tr>
</tbody>
</table>

The IIEF-5 score is the sum of questions 1 to 5. The lowest score is 5 and the highest score is 25.

1-7: Severe ED  8-11: Moderate ED  12-16: Mild-moderate ED  17-21: Mild ED  22-25: No ED
Membership of the guideline development group

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Declared conflicts of interest

TJ Dorkin has received honoraria for speaker meetings from Pfizer and Lily.

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