Assessment and treatment of Erectile Dysfunction (ED)

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Assessment
Why do we bother asking about ED?

“Sexual Health is the integration of the somatic, emotional, intellectual and social aspects of sexual being, in ways that are positively enriching and that enhance personality, communication and love”

(W.H.O.1975)
How does the new ED patient presenting for the first time feel?

- Nervous and embarrassed
- Agitated
- Desperate and lack of confidence
- Ashamed and secretive about the condition
- Guilty
- Depressed
- Avoiding intimacy with their partner
- Avoiding seeking help and may have mood swings
- Giving a different reason other than ED for visiting the doctor/nurse
- Scared may be more than ED, perhaps a life-threatening condition
- Will often cancel the appointment
Partner

• Feels rejected
• Feels to blame
• Fear of losing the relationship
• Is the man having an affair?
• How can he/she address the issue?
• What does the future hold?
• Depression and feels unattractive
• Feel that it is their fault
• This may be occurring in their male partner, just as they are going through the menopause
Typical quotes from ED patients:

“I feel less like a man because I can’t get an erection”

“I feel I am letting my partner down”

“My partner thinks it’s their fault”

“I try to avoid sex to stop myself feeling disappointed”

“We are not as close as we used to be”
Reluctance of professionals – Why?

Barriers to addressing sexual issue include:

- Inadequate training / lack of knowledge
- Embarrassment
- Fear of offending
- Not relevant/applicable
- Language barriers - culture, jargon, slang
- Attitude to subject
- Needs an expert
- Private matter to patients and invading patient’s privacy
- No supervision to explore the concept
- Time constraints

(Bell and Entwistle 2000-01)
The “Can of Worms”

- Age
- Gender
- Confidentiality
- Language
- Religion
- Culture
- Embarrassment
- Time
- Appropriateness
- Respect/empathy
- Shame
- Assumptions:
  - Too old
  - Too young
  - Disabled
- Availability local resources
- Adequate and updated training
- Attitudes and Values
- Doctor/ Patient powerbase

(Mary Clegg PG Dip PST 2010)
Treatments
2 Years
Where to begin?

- What is the problem and what ‘bothers’ them?
- Patient’s definition – clarify
- Partner’s perception
- Patient Goals
- Previous treatments? What and where from?
- Expectations of treatment
- Situational?
Assessment - general

- Medical / surgical history
- Medication / allergies
- Social
- Relationship
- Smoker / Alcohol / Recreational Drugs
- Psychological factors
- Family history
Assessment - comprehensive

- Testosterone – check local assay values
- FSH, LH, SHBG
- Prolactin
- TFT’s
- RBS
- Lipids
- Luts / DRE
- Clinical examination
WHAT DO MEN WANT?

Is your wand not working like it should?

...Does it quit on you at all the wrong times?

We have a spell that will finally help you perform when it really counts.

Spell-casting Dysfunction (ScD) is a real and serious problem for wizards of all ages and varieties. Whether you’re a Gryffindor, a Hufflepuff, a Ravenclaw, or a Slytherin, no wizard is completely immune.

That’s why we at Pfizer, division of Hoechst-Roussel and Pfizer, Inc., have introduced a special counter-spell, in the bottle that will make your wand stiff and strong for your next battle against evil sorcerers and their minions.

WIZAGRA: Putting the sap back in your magic wand.
The European Association of Urology recommend that first-line drug treatment for ED is with an oral PDE5 inhibitor (PDE5i).  

However, around 25% of patients do not respond to PDE5i therapy and not all men tolerate or are able to take a PDE5i due to contraindications.

The EAU recommends intracavernous injection of or intraurethral administration of alprostadil as second-line therapy.

The EAU have not yet reviewed topical alprostadil cream.

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Image adapted from EAU Guidelines

<table>
<thead>
<tr>
<th>1st Line Treatment</th>
<th>2nd Line Treatment</th>
<th>3rd Line Treatment</th>
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</thead>
<tbody>
<tr>
<td>PDE5 inhibitors</td>
<td>Topical alprostadil</td>
<td>Penile prosthesis</td>
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<tr>
<td>Vacuum erection devices</td>
<td>Intracavernous injection therapy</td>
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<tr>
<td></td>
<td>Intraurethral alprostadil</td>
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Identify and, where possible, manage any reversible or modifiable risk factors, including lifestyle or drug-related factors

https://cks.nice.org.uk/erectile-dysfunction
What are men looking for in ED Treatment?

Men consider the following to be important dimensions of successful treatment:

- Cure - return to normal sexual function
- Pleasure - eg, sensation, orgasm achieved
- Partner satisfaction
- Reproduction - ability to ejaculate
- Naturalness
- Control
- Duration
- Spontaneity

Hanson-Divers C et al 1998 Journal of Urology 159:1541-1547
Patients who can be prescribed treatment for erectile dysfunction on the NHS (all medications and vacuum devices)

<table>
<thead>
<tr>
<th>Prostate cancer</th>
<th>Spinal cord injury</th>
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<tbody>
<tr>
<td>Prostatectomy</td>
<td>Diabetes</td>
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<tr>
<td>Multiple sclerosis</td>
<td>Spina bifida</td>
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<tr>
<td>Polio</td>
<td>Parkinson’s disease</td>
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<tr>
<td>Severe pelvic injury</td>
<td>Radical pelvic surgery</td>
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<tr>
<td>Single gene neurological disease</td>
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<tr>
<td>Renal failure treated by dialysis or treatment</td>
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+ all other men with ‘severe distress’ - exceptional circumstances (after specialist assessment)

+ all patients on treatment from GPs on 14th Sep ’98

• Sildenafil Citrate removed from Schedule 2, Aug 2014
Oral medication for the treatment of erectile dysfunction
Oral Medication – PDE5i’s

Cialis® Tadalafil - prn or daily dosing (Lilly)

Levitra® Vardenafil - oral or oro-dispersable (Bayer)

Spedra® Avanafil – prn (Menarini)

Viagra® Sildenafil - now off patent, prescribe Sildenafil – beware only

80% active ingredient
PDE5 inhibition: General principles

# PDE5 Inhibitor Pharmacokinetics*

<table>
<thead>
<tr>
<th></th>
<th>Vardenafil</th>
<th>Avanafil</th>
<th>Tadalafil</th>
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</thead>
<tbody>
<tr>
<td>$T_{\text{max}}$</td>
<td>60 minutes</td>
<td>3 – 5 hours</td>
<td>120 minutes</td>
</tr>
<tr>
<td>$T_{\frac{1}{2}}$</td>
<td>4 – 5 hours</td>
<td>60 minutes</td>
<td>17.5 hours</td>
</tr>
</tbody>
</table>

*Based on SmPC for each product
PDE 5i’s – Avanafil, Tadalafil, Vardenafil

**Advantages**
- Ease of use
- Few side-effects
- Acceptance by partner
- OAD – ‘forget the ED problem’
- Can be kept as a personal secret

**Disadvantages**
- Unable to use for patients on nitrates
- Delayed response / pre planning
- Interaction with food
- Ineffectiveness /
- Side-effects: uncommon
- Cost
First-time success in ED therapy matters

“When, according to the patient, treatment did not work, the distress was severe and for many confirmed their lack of self worth”.

“There was an assumption they had to take only one pill for all to be well. When this did not happen, hopes fell”

When a treatment does not work first time, 77% of men worry that their ED might be permanent

2. Data on File, Bayer Schering Pharma August 2007
Optimising success/managing PDE5i “failures”

Patient Education

Sexual stimulation is needed

Absorption affected by food (drugs vary)

Post-dose timing (drugs vary)
Optimising success/managing PDE5i “failures”

Several attempts may be required for optimum effect

Dose optimisation

Consider an alternative PDE5i if first drug is unsatisfactory
Patient education is paramount…

…PDE5 inhibitor ‘failure’ may be a lack of education
That's odd. This bottle of Viagra was full two days ago.
Intraurethral (IU) therapy - alprostadil

MUSE (Medicated Urethral System for Erection)

Applicator for intraurethral delivery of alprostadil. Depressing the end releases the pellet into the urethra.

Pellet of alprostadil inside the urethra.
Transurethral application of alprostadil - MUSE®

Advantages of MUSE® therapy

- Speed and ease of use
- Comfort of application
- Acceptance by partners
Disadvantages of MUSE® therapy

Penile ache or pain - approx 30% of patients experience this

Need to keep very cool - ideally in fridge

Need to void prior to insertion

Cannot be used if partner pregnant

Variable response
Topical Alprostadil Cream - Vitaros®
Vitaros® is the non-invasive cream for men with ED ¹

Vitaros® is a 100µL drop of cream that combines 300µg of alprostadil with a novel permeation enhancer, NexACT®-DDAIP¹

Vitaros® is licensed for the treatment of men ≥18 years of age with erectile dysfunction¹

- Vitaros® is applied to the tip of the penis (meatus) where it is rapidly absorbed without invasive delivery¹
- Vitaros® should be applied 5 to 30 minutes before sexual intercourse¹

Mode of Action

- Vitaros is a topically delivered formulation (cream) of alprostadil supplied in a single dose dispenser (AccuDose™)

- Alprostadil is a synthetic vasodilator chemically identical to the naturally occurring prostaglandin E₁ (PGE₁)₁,²

- The actions of PGE₁ include vasodilatation of blood vessels in the erectile tissue of the corpora cavernosa
  - An increase in cavernosal artery blood flow
  - Relaxation of the sinusoidal smooth muscle, resulting in an erection.¹,²

- Alprostadil does not rely on nitric oxide or an intact nervous system

- Delivered with NexACT-DDAIP delivery technology¹
  - Enables rapid penetration of higher concentrations of active drug directly through the skin and major biological membranes

The onset of effect is within 5 to 30 minutes after application. The duration of effect is approximately one to two hours.

**Note:** urinating directly after application will significantly reduce the effect, urinate before applying the cream.
Vitaros®
– topical Alprostadil Cream

* Launch June 2014.
* Store in fridge, stable at room temp. 3 days.
* Gently squeeze head of penis, so that meatus opens, acts like a “cup”.
* Drop cream into “cup”.
* Do not insert applicator into urethra.
* Rub into head of penis after 30 seconds.
* 5-30 mins to work.
* Dose - 300ug
Vitaros®

- Irritation, burning sensation or itching around your and/or your partner’s genitals;
- dizziness;
- fluid accumulation in the penis.
- may cause temporary dizziness. Do not drive or participate in traffic for two hours after application.
- Most side effects will disappear within a few hours.
No food or alcohol restrictions. However, alcohol has a negative effect on erection quality.

Can be harmful to the unborn child. Vitaros® cream should therefore only be used on doctor’s advice if partner is pregnant, wants to become pregnant or is breastfeeding. Use a condom barrier for sexual intercourse to prevent exposure.
Injection Therapy
Drug injected directly into the corpus cavernosum away from midline

e.g. alprostadil
Advantages of injection therapy

Natural looking and feeling erection

Ease of use once practiced

Natural erections can improve and recover with use
Disadvantages of injection therapy

- Needle phobia
- Pain and burning at site
- Anatomical problems
- Bruising and swelling of penis
- Ineffectiveness
- Difficulties with technique
- Partnership problems
- Unpredictability
Vacuum Therapy
Vacuum Erection Devices
Place Flaccid Penis in Cylinder
Create Negative Pressure to Achieve Engorgement
Apply Pressure-Point Tension Ring to Maintain Rigidity*
Acceptability, Advantages of devices

* It works!
* Puts man back ‘in charge’ of his erections
* Leads to improvement in natural erections very often
  * Use as a ‘love aid’ – partner participation
  * Can improve penile length
Disadvantages.
VTD - Disadvantages

- Mechanical device - integrate
- Penis can change colour
- Penis can be flexible, pivots
- Penis can feel cold
- Painful
- Initial cost
- Unable to sustain the erection.
- Noisy – battery operated
- Blockage of ejaculate
Penile Prosthesis

* Semi – malleable - out at length
* Inflateable – mimicks normal erection
Semi-maleable implants
Semi - Malleable
Inflatable Penile Prosthesis
Penile Implants

Multi-part inflatable prosthesis

Reservoir

Cylinders

Pump
### Penile prosthesis implantation

#### Advantages

- Useful when other treatment options have failed or are contra-indicated
- High success rate
- Provides a ‘one-off’ solution

#### Disadvantages

- Higher incidence of morbidity and complications than with medical treatment
- Possible mechanical malfunction of the prosthesis
- Erosion
- May require replacement
- Possible infection
- Soft Glands
- High cost / training / annual review
- Patient and partner acceptance
- Psychological
Other options

- Combination Therapies; off licence, usually initiated in Specialist services.
The Importance of Patient Preference in the Treatment of ED

“No one else can insist or decide on a treatment on behalf of the patient, nor ultimately interpret success. In this regard, ED differs from almost all other medical diseases and it’s implications are far reaching”

Thanks for your attention!

Any Questions?