NHS services for erectile dysfunction: a case of orchestrated chaos?

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Existing regulations designed to control the costs of therapy for erectile dysfunction mean that GPs are referring men to secondary care clinics for fear of missing a qualifying condition, thus increasing the overall cost of care.

As the Prime Minister laid out the difficult way ahead for the NHS, many patients waited eagerly for news that erectile dysfunction (ED) services would be protected at all costs. However, there was never any chance of this happening, and I must admit that if I were the chief executive of a hospital trust, I might identify these so-called ‘lifestyle conditions’ for severe cuts.

Unfortunately, ED does not come under the umbrella of sexual health; a review of the many NHS documents of the past 20 years reveals that sexual health embraces contraception, unplanned pregnancy and sexually transmitted infection, including HIV, but not the management disorders of sexual function, such as ED.

HEALTH SERVICE CIRCULARS 1999/115 AND 1999/177

After the first oral drug to treat ED had been licensed in 1998, the Rt Hon Frank Dobson, Secretary of State for Health, introduced Health Service Circulars (HSC) 1999/115 and 1999/177 to control the demand for these ‘lifestyle’ drugs (Boxes 1 and 2).

Many of us felt that it would have been more honest simply to say that the NHS could not afford the drugs, but certain random categories (mainly neurological conditions) were singled out as qualifying for NHS prescriptions. Vascular causes of ED (around 80 per cent) were deemed less deserving and would require self-funding at private rates.

As if these prescribing restrictions did not create enough difficult consultations with men, they were followed up with the concept of ‘severe distress’, which would require long-term, even lifelong, secondary care follow-up by specialists, with complex repeat prescribing issues being put in place for this class of drugs. Many hospitals reasonably decided that it was financial folly even to contemplate a service, but those that were already offering such services decided to embrace the regulations for the good of their patients.

Several evidence-based guidelines came and went (notably not from the National Institute for Health and Clinical Excellence), but only Mr Dobson’s have any real impact on health care. Twelve years on, and with no change, in spite of a couple of promised reviews, it is time to assess whether these documents were just simply the most inept in the history of the NHS or a cunning plan to divide and conquer well-meaning healthcare professionals.

IMPLICATIONS FOR PRIMARY CARE

Over the past 15 years, it has been clearly established that persistent ED is, in more than 80 per cent of cases, a manifestation...
of cardiovascular disease, occurring two to three years before coronary artery disease and five years before a coronary event. Rather than introducing questions about ED as part of chronic disease assessment and over-40s health checks, the UK has lagged behind the rest of the world by not embracing the evidence for fear of opening ‘Pandora’s box’.

Many men present with ED in their 30s or 40s, often as a result of pressure from their partners, rarely because of direct questioning from a healthcare professional. Having paid into the NHS for all their working lives, they now discover that they have the only condition for which they will have to fund all their treatments privately. The condition might well have been a result of cost-effective prescribing for hypertension or depression, but somehow this makes no difference.

The GP now faces an awkward consultation around the whole ethos of the NHS concept of ‘free health care at the point of delivery’. He then wonders if he can remember the regulations precisely, so it might just be a good idea to seek a ‘second opinion’ from a specialist. Some might call this an example of ‘enabling patient choice’; some might call it ‘passing the buck’. At this stage, he might forget to take blood to check lipids, fasting glucose or testosterone, as the specialist guidelines suggest.

**IMPLICATIONS FOR THE SPECIALIST**

According to HSC 1999/177, the specialist may be a urologist, psychiatrist, genitourinary or endocrine physician, or a commissioned GP. The designated specialist is now faced with the patient with no investigation results; these will need to be done, as the management will depend on the findings. This is an opportunity to delay the issues until a follow-up consultation. When the bloods are completed, the specialist finds that the patient is glucose intolerant, alas not diabetic yet, has borderline dyslipidaemia at a level that GP guidelines deem unsuitable for primary prevention, and has a slightly low, but not treatable, testosterone level. A rapid decision, involving an off-the-cuff means test, now needs to be made. The specialist explains all the treatment options and offers the patient a private prescription, which he might accept; on the other hand, he might walk out, saying ‘I’ve paid my taxes for years’ or ‘I fought for my country’.

Some challenging scenarios have resulted from the prescribing restrictions introduced by HSC 1999/115. For example:

- Men may suffer glucose intolerance and decide to solve the issue by inducing mild diabetes by dietary excess, modifying their lifestyle afterwards.
- They may persuade their GP that cycling for many years has caused pelvic trauma severe enough to lead to ED.
- The ED treatment may have been prescribed before 1998; the patient’s wife has since died and he has met somebody else.
- The patient may request transurethral resection of the prostate for benign prostatic hyperplasia, even if drug therapy is working well.

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**BOX 1. Restrictions on NHS prescribing of drugs for erectile dysfunction**

All drugs for treatment of erectile dysfunction are classified as schedule II. They may be prescribed on the NHS only in men who:

- were receiving NHS prescriptions for one of these drugs on 14 September 1998 (regardless of diagnosis)
- are suffering from any of the following:
  - diabetes
  - multiple sclerosis
  - Parkinson’s disease
  - poliomyelitis
  - prostate cancer
  - severe pelvic injury
  - single gene neurological disease
  - spina bifida
  - spinal cord injury
- are receiving treatment for renal failure by dialysis
- have had the following surgery:
  - prostatectomy
  - radical pelvic surgery
  - renal failure treated by transplant
- are suffering from severe distress (diagnosed by a hospital consultant)

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**BOX 2. Prescribing for men with severe distress**

Men who are not eligible for NHS prescriptions of drugs for erectile dysfunction can receive treatment from specialist services where their impotence is causing severe psychological distress:

- significant disruption to normal social and occupational activities
- marked effect on mood, behaviour, social and environmental awareness
- marked effect on interpersonal relationships

Treatments to be authorised and monitored by NHS specialist at hospital cost unless by local negotiation (but no budget)

Patients to be reviewed regularly for change in circumstances
• The man may have moved to a different area. Is a new hospital bound by the decision of a now-retired doctor in 1998 who felt that the patient was severely distressed? What happens if he has moved to an area where the local hospital does not operate a service?

We have seen several patients who have complained about GPs who failed to pick up a qualifying condition, and the patient had to pay privately for three years. The GPs had to personally repay the patients more than £1000 each. No wonder GPs opt to refer most patients for specialist interpretation of the government guidance on ‘good practice’!

A final question from the specialist could avert these problems: ‘Mr B, do you think that you might be suffering from severe distress?’ This usually results in a denial along the lines of: ‘The wife and I are not happy, but distressed ... no’. On hearing that the private prescription will cost him £40–50 per month, the patient replies: ‘You know, I think I probably am severely distressed; in fact, the wife is so distressed, I left her in tears at home’. Off he goes to the pharmacy with a hospital prescription and repeats arranged for several months (your earliest follow-up appointment). If the tablets do not work or he has side-effects, around £100 worth of medication will be wasted.

Other patients arrive better prepared: ‘Good afternoon, Dr H. Before we go any further, let me just make it clear that this problem is causing me severe distress – just write that down, severe distress’. This man has a GP who has orchestrated everything for us; no off-the-cuff means test required here.

A common reason for referral to secondary care is failure to respond to a phosphodiesterease type 5 (PDE5) inhibitor, often caused by testosterone deficiency. The consequences of diagnosing this is that it will now cost £75–100 per month to treat the patient, and the GP will be left with ongoing long-term prescribing and management to achieve testosterone levels in the normal range. Unless this is achieved, the cost of the PDE5 inhibitor will be wasted, as it has already been established that the PDE5 inhibitor did not work alone in this patient. Unfortunately, there is potential for more wastage, as both conditions need to be managed by primary care physicians, who may not be motivated to carry out the additional work and prescribe at this level to resolve what many still see as a ‘lifestyle’ issue.

DIFFICULTIES ASSOCIATED WITH COMMISSIONING

The concept of commissioning under the 2004 GP contract introduced further complications. The introduction of internal market principles has not been suited to ED. The pathway of care is only for the man, yet anybody trained in managing sexual problems knows that they are at least as common in the partner and there are many pitfalls in not addressing the issues in both partners.

Fewer than 20 per cent of men attend with a partner, and the ED specialist must not treat or offer advice to the partner as they have no commissioned pathway of care. Offering a likely partner diagnosis to the man is ill advised and may harm the relationship. If sex therapy or psychological therapies are thought to be indicated for either or both, this must be redirected back to the GP for referral down the pathway commissioned by the primary care trust (PCT). Worse still, there may be no pathway, just a suggestion for the couple to attend Relate. There is likely to be little or no continuity of care, and the man will probably receive large quantities of medication from the hospital pharmacy, much of which may be inappropriate. It is unlikely that any of these issues will be seen as a priority when GP commissioning groups renegotiate care pathways over the next two years.

ONGOING CARE ISSUES

There are few publications on this subject, possibly as most hospital trusts spotted the flaws in the regulation from the outset, but the author has reviewed many of the recent issues, including the logistics of appointment and funding. Of course, PCTs will be delighted to pay for an £85 follow-up consultation if the hospital funds £400 worth of drugs per year.

Hackett and Cole reviewed referrals to an NHS ED clinic over two years (Table 1).4 Twelve years of this system could mean 600 patients and a financial loss to the hospital of more than £280 000 per year. No wonder the ED clinic represents a prime target for service cuts.

Some hospitals converted to ‘nurse-led clinics’, meaning that the nurse was not qualified to prescribe. In some cases this worked and GPs took over the prescribing, but usually only until the next medicines management audit. One local PCT looked at the situation and saw this clearly as a GP prescribing issue, and agreed to take all the patients back. This has created a very clear ‘postcode inequality’, with many patients changing their GP purely for this reason.

<table>
<thead>
<tr>
<th>Reason for referral</th>
<th>No. of patients (%)</th>
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<tbody>
<tr>
<td>Severe distress</td>
<td>145 (54)</td>
</tr>
<tr>
<td>Failure to respond to PDE5 inhibitor</td>
<td>74 (27)</td>
</tr>
<tr>
<td>Management issue</td>
<td>22 (8)</td>
</tr>
<tr>
<td>Unclear</td>
<td>21 (7)</td>
</tr>
<tr>
<td>Difficulty with diagnosis</td>
<td>11 (4)</td>
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Table 1. Reasons for referral to an NHS erectile dysfunction clinic
ED is now known to be a strong marker for future cardiovascular events, and many men with ED have an abrupt change in their cardiac condition at a time between their annual follow-up visits. The GP will have made sure that the PDE5 inhibitor is not recorded on the repeat prescription and rarely mentions it to the hospital in letters. The patient has the right to feel confident that each member of his team of doctors knows what the other is prescribing, so he accepts the cardiology department prescription for a nitrate, while continuing to pick up outpatient scripts for a PDE5 inhibitor. Unfortunately, the issue of who pays for the drugs has become more important to many than patient safety. After documenting several of these cases and declining to issue repeat prescriptions for a nitrate, while continuing to pick up outpatient scripts for a PDE5 inhibitor, high-profile tragedies have tackled the issue. High-profile tragedies are more likely to alter the economics and should bring appointments for more urgent conditions are being wasted.

CONCLUSIONS
There can be few better examples of misguided government interference with evidence-based medicine than HSC1999/115 and HSC 1999/177. Those secondary care providers who spotted this at the outset made wise decisions. It is paradoxical that effectively the former document on qualifying conditions for NHS therapy has been followed by the vast majority, but those who have tried to implement the latter have struggled, such that by 2011, only a handful of clinics in the country persevere with it. These documents are described as being ‘intended for guidance on good practice’. The tragedy is that excellent, hard-working, motivated clinicians have endured this piece of ‘evidence-free’ legislation for so long, often with deep divisions between clinicians, and wasted many hours explaining this misguided legislation to their long-suffering patients.

Declaration of interests
Geoff Hackett is an occasional speaker for Bayer and Lilly and has received a research grant from both companies.

REFERENCES