Victorian Senior Practitioner

Anti-libidinal medication use in people with intellectual disability who sexually offend

Report by Dr Stuart Thomas and Professor Michael Daffern

June 2014
Anti-libidinal medication use in people with intellectual disability who sexually offend

This review was commissioned by the Victorian Government Department of Health and Human Services in response to the significant issues associated with the prescription and monitoring of these medications with this population. This review was completed by Dr Stuart Thomas Faculty of Social Sciences, University of Wollongong, NSW, and Professor Michael Daffern School of Psychology & Psychiatry, Swinburne University.

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In this document, 'Aboriginal' refers to both Aboriginal and Torres Strait Islander people.

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Foreword

Sexual offenders with an intellectual disability are very much a maligned group. They are subject to longstanding negative myths and stereotypes, when ironically they belong to a group of people who perhaps more so than any other group, are more likely to be victims, rather than perpetrators of sexual offending. It has been well established in the research literature that a significantly higher proportion of sex offenders with an intellectual disability have histories of childhood victimisation compared with mainstream populations.

Today the assessment and treatment picture for this population is much improved. There have been recent advances in risk assessment methodologies designed specifically for this group. It is also clear that nearly all sexual offenders with an intellectual disability are able to engage in established psychotherapeutic treatment programs that can result in significant treatment outcomes. Many are able to move on to less restrictive and even unsupervised day-to-day settings.

The use of anti-libidinal medications with this population is controversial. Research within this area is sparse and, what research there is, is equivocal. However, treatment providers find, for at least a small group within this population, that the use of anti-libidinal medications can facilitate the effects of these psychotherapeutic treatment programs. There are, however, significant side effects associated with these medications, which may also have a greater impact with this population. Given these considerations it is of utmost importance that the use of these medications be carefully prescribed and monitored.

It is within this context that this project is of great importance. Establishing guidelines and standards for prescribing and monitoring anti-libidinal medications in this population will greatly assist in maintaining the focus on the rights and needs of those undergoing this treatment.

I would like to thank in particular the research team, Professor Stuart Thomas and Associate Professor Michael Daffern, for bringing this project together, and also the participants in the Delphi study, who contributed their practice experience to this process.

Dr Frank Lambrick
Senior Practitioner – Disability
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Department of Health and Human Services
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Introduction

The requirement to identify, manage and treat people who have inappropriate sexual behaviour pervades contemporary clinical practice in criminal justice, mental health and disability services. It also has a long tradition of heated dialogue between the various stakeholders, raising particularly strong emotional responses from community members who demand a safe community and assurances of protection from potential victimisation experiences. Expert and judicial efforts to manage this small but significant group of offenders has increasingly been informed by the state of the available evidence which, more often than not, is frustratingly slow to emerge and therefore not responsive to the more immediate needs for legislative and policy review and change.

As a group, and regardless of level of disability, people who sexually offend are highly stigmatised; traditionally the dominant approach to their management has been punitive as opposed to being treatment and/or client focused. Some have argued that this emphasis on punishment has contributed to a significant shortfall in the availability of good-quality research evidence being made available. Others point to the distinct lack of specialist services being available to house, treat, manage, supervise and support this select group of offenders. These service limitations are not peculiar to Australia, with many international commentators noting the lack of available funds to support specialist services (see, for example, Hayes 2004). One of the most significant shortfalls in service provision relates to people with an intellectual disability who sexually offend. In a compelling paper, Susan Hayes (2004, p. 85) adapted John Gunn’s (2000) argument about the availability of services for people with mental disorders to consider the core factors that influence the availability of placement options for people with intellectual disability. She argues that the continued limited range of specialist services available reflects: (1) sustained public notions of dangerousness and the continued stigmatisation of those who are different; (2) that society cares less for its vulnerable members; (3) that caring professionals are increasingly viewing some people as untractable, too difficult, or difficult to like; and (4) prison may be being perceived by the public sector and politicians as a cheaper option.

Treatment options

The aim of treatment, regardless of presenting severity, should always be the same, namely: (1) to reduce inappropriate sexual behaviour; (2) to suppress inappropriate sexual urges and behaviour; and (3) to reduce the risk of further victimisation (Bradford 2000, p. 250). The focus of intervention efforts over the years have predominantly considered the application of psychological interventions and biological treatments. Pharmacological approaches to treating sexual offending are based on extensive scientific knowledge that hormones and neurotransmitters are central biological components of sex drive (Bancroft 1989). As such, anti-androgens and hormonal therapies form the main treatment options (Bradford 2000). While the focus of this review is on anti-libidinal medications, a brief overview of the role of psychological approaches is first deemed appropriate.

Psychotherapeutic approaches have long played a significant role in the treatment approaches targeted at sexual offenders. According to Rice and Harris (2003), one can only be truly confident of the efficacy of a treatment if it has been subjected to the methodological and procedural rigours of a randomised controlled trial. To these ends, a recently published Cochrane review of studies relating to the treatment of sexual offending in the general offender population (Dennis et al. 2012) found only 10 studies that were of sufficient rigour (randomised controlled trial quality) to be considered eligible for inclusion; this resulted in a total pooled sample size of 994 people. These studies were dated, having been published up to 40 years ago, between 1974 and 1997. Of these, the studies that reported the use of cognitive behavioural therapy (CBT) as an intervention found no significant differences in the risk of reoffending when compared with those not receiving the CBT interventions. However, studies that had used behavioural interventions demonstrated what Dennis and colleagues (2012) referred to as more ‘encouraging results’.
There is little or no argument that the controlled trial rigour proposed by Rice and Harris (2003) should be considered the ideal ‘gold standard’ of testing the effectiveness of a treatment intervention. However, there are a number of practical, financial and ethical impediments associated with this methodology that significantly hamper opportunities to conduct a trial according to the required CONSORT guideline <http://www.consort-statement.org> (also see Schulz, Altman & Moher 2010) and with adequate statistical power. In their stead, it has been argued that other robust methodologies can still contribute meaningfully to an evidence base (see, for example, Black et al. 1998) and can provide sometimes compelling information pertaining to outcome-related data (such as recidivism).

It is interesting, therefore, that including a broader suite of research methodologies (for example, case studies, cohort studies and case-control approaches) in a review of the effectiveness of psychological interventions for sexual offenders has led to a different conclusion from that reached by the recent Cochrane review. For example, Hanson and colleagues (2002) concluded that CBT interventions had the greatest effect on recidivism. Added to this, in an updated study, Losel and Schmucker (2005) described psychological treatments that showed more promise and concluded that psychological treatments were moderately effective in reducing recidivism. This conclusion was shared by Thibaut and colleagues (2010), who noted a modest reduction in recidivism associated with their application as an intervention. Of note here, however, the Thibaut paper questioned the durability of these ‘treatment gains’ in the medium to long term that had not been routinely considered in the available literature, although there is a strong consensus of the need to factor in the requirement for booster sessions – a practice that is common in psychological treatments (see, for example, Whisman 1990).

Specifically focusing on research on sexual offenders with intellectual disability, Ashman and Duggan (2008) failed to identify any randomised controlled trials to appraise the effectiveness of treatment interventions with this population. As such, their recommendation was that clinicians would need to continue to extrapolate from study findings that reported on the efficacy of interventions with non-intellectually disabled populations. Furthermore, they advocated for a more nuanced consideration of the potential value of any evidence that was available from studies that had utilised alternative (non-trial-based) research methodologies.

The scientific evidence base around the use of anti-libidinal medications with people with intellectual disabilities remains limited. The results of the few available ‘controlled’ studies do not provide compelling evidence for supporting the efficacy of their use (Bradford & Pawlak 1993; Cooper 1981; Hucker, Langevin & Bain 1998). These studies were also published at least 20 years ago (and therefore conducted several years before those publication dates), so their applicability in the current (Australian) context is extremely limited. The available research is significantly hampered with respect to both rigour and robustness, and therefore generalisability. Methodologically speaking, sample sizes have generally been small and opportunistic in nature, with little if any follow-up; they have been hampered by high refusal and attrition rates and, as a result, have only been able to capture what essentially amounts to short durations of treatment. While the possibility of conducting a randomised controlled trial of the efficacy of anti-libidinal medication would clearly have significant ethical and health-related concerns, some influential authors assert that without this level of evidence there should be little confidence in their application in routine clinical use for treating sexual deviance, especially as a principal component of any treatment program (Hayes 1991; Rice & Harris 2011).

A number of other studies utilising alternative methodologies have, however, suggested some positive benefit associated with these medications. Thibaut, Corbier and Kuhn (1996) describe six cases where individuals were treated with gonadotropin-releasing hormone drugs (GnRHa); in five of the six cases inappropriate sexual behaviour ceased and there were markedly decreased sexual behaviour and activities reported, importantly with no significant side effects identified; an earlier review by Clarke (1989) also reported that a small number of cases benefited from anti-libidinal medication treatments. Bradford (2000) reported beneficial responses to cyproterone acetate in reducing paraphiliac behaviour (decreased erections, sexual behaviour and sex drive) arising from a dated study by Laschet and Laschet (1975) and reported that this medication was also an effective treatment in severe paraphilias.
(Bradford & Pawlak 1993). Harrison (2007) suggests that findings indicate a small selective target group for whom these medications may be beneficial; she suggests this group are preferential paedophiles (those who have sexual relationships with children, never adults). Collectively, while arguably being limited in generalisability (when conceptualising a traditional continuum of research rigour/sophistication), these study findings are potentially clinically useful in that they suggest a particular target group of sexual offenders for whom anti-libidinal treatment regimens appear to have discernible benefit. The best treatment outcomes have been found in situations where anti-libidinal medications have been administered alongside psychotherapeutic interventions (Glaser 2003; Harrison 2007). Weiss (1999) asserts that this may be due to the anti-libidinal treatment suppressing sexual urges and desires which, in turn, allows for greater concentration on other therapeutic activities that are aimed at controlling inappropriate sexual behaviours.

**Potential for side effects**

One of the most significant concerns raised with the use of anti-libidinal medications relates to the potentially significant deleterious effects experienced by the patient on their health and quality of life, described by some as ‘substantial’ (Gijs & Gooren 1996). Some of the wide-ranging side effects that have been reported include weight gain, migraine headaches, gallstones, formation of blood clots, serious allergic reactions, depression, suicidal thoughts, hypertension, diabetes, difficulties with breathing, insomnia and shrinkage of prostate vessels (see, for example, Spalding 1998).

Negative effects on the person’s quality of life have perhaps been less emphasised, in spite of the dramatic secondary impacts the side effects of weight gain, fatigue and gynaecomastia (reported to be irreversible according to Craissati 2004) can and do have on subjective indices of self-esteem and mood. Rainey and Harrison (2008) suggest that, while not reaching the extent of constituting torture under international human rights legislation, the impact of these side effects could be considered degrading and inhumane. However, the European Court of Human Rights held that, as a general rule, this would not be the case in situations where the medication was considered to be a therapeutic necessity (Herczegfalvy v Austria (1992) 15 EHRR 437). Rainey and Harrison (2008) indicate that ‘therapeutic necessity’ could be conceptualised both in terms of the assessment of medical suitability of the individual as well as demonstrating the effectiveness of the medication on that person; they also emphasise the importance of consent in these considerations from a human rights perspective.

Authors have noted the additional concern that should be raised with respect to the side-effect profiles of these medications when people present with intellectual disability. As a group, people with intellectual disability are at far greater risk than the general population for suffering from a wide range of health-related disorders across the lifespan (and especially with advancing age) including seizures, mobility impairment and neurological anomalies (Janicki et al. 2002). The potentially greater impact on their health associated with taking anti-libidinal medications, especially for longer periods of time, is therefore particularly problematic because there remains a poor understanding of the long-term consequences of taking these medications (Grossman, Martis & Fichtner 1999). A further, often quoted, complication relates to the timely identification of side effects that do arise, especially those that don’t manifest in an externally visible or physiologically measurable way, as many people with intellectual disability may not be able to understand what they are experiencing and/or be able to report their occurrence to their clinician, support workers or carer due to specific communication impairments (see, for example, King 2007). Indeed, their attempts to otherwise express their experience of unpleasant side effects can often be misinterpreted as challenging behaviour (Carlson, Taylor & Wilson 2000).

Taken altogether, these issues raise significant clinical concern about the appropriateness of prescribing these medications to people with intellectual disability. While some assert that, because of the lack of evidence, these medications should not be used at all, others contend that because numerous case studies have demonstrated benefit for certain high-risk offenders, these medications do have a role to play in certain highly specific treatment situations. That being said, a great number of authors (Prentky 1997) have concluded that these medications should never be used as an exclusive treatment, even
though this can sometimes be considered an ‘easier option’ when services lack the resources for providing additional/alternative psychotherapeutic interventions (Gumber, Gangavati & Bhaumik 2011).

What is clear is that the available evidence stipulates that anti-libidinal medications should not be used in males under the age of 18, or in other instances where bone and testicular development have not yet completed (Glaser 2003). However, there have been cases anecdotally reported where these cautions have not been observed. The potential for abuse among prescribers (pertaining to the inappropriate prescription of these medications to suppress what amounts to normal sexuality) has also been noted in the literature (Gumber et al. 2011; Hayes, Barbouttis & Hayes 2002).

**Status quo**

Due to the aforementioned limited evidence base, it has been strongly recommended that anti-libidinal medications only be used as part of a multifaceted treatment, management and support plan under close supervision and with regular monitoring (Hayes 1991; Sajith, Morgan & Clarke 2008). Lindsay (2004, p. 179) argues that further case examples, as well as controlled trials, are required (and informative) to help more fully appreciate the range of effectiveness of pharmacological interventions among people with intellectual disability. Case studies and clinical experience in isolation have indicated differential treatment gains and tolerance of anti-libidinal medications at the individual level. There also still remains the need for controlled studies to better inform treatment options and efficacy from both psychological and pharmacological approaches (Ashman & Duggan 2008; Cooper 1995).

To help facilitate decision making in the current climate, there has been a call to develop and operationalise guidelines and protocols regarding anti-libidinal medication prescription and the close monitoring of side effects arising from this (Gumber et al. 2011).

**Rationale for current consultation**

Given that the current policy and legislative climate focuses on increased patient autonomy and encouraging the active participation of patients in decision making about their care and treatment, there needs to be much more of a focus on social and human rights-based considerations regarding decision making around prescribed treatments. All services should ultimately work towards the same goals to best meet the needs of their client group and should therefore base their intervention strategies on the available evidence base. It is highly unlikely that any one service alone can adequately cater for the needs of this client group, so collaborative efforts are an inevitable component of a multifaceted service delivery model. To achieve such a goal across services, a coherent set of guidelines are arguably a necessity. It is somewhat surprising therefore that what remains lacking at the current time, certainly in the Australasian context, are guidelines pertaining to the prescription and monitoring of the risks and benefits of anti-libidinal medication use with intellectually disabled offenders who present with sexual deviance.

A targeted review of the literature outlining available guidelines internationally identified two potential guidelines that could be considered as the basis for proposing guidelines for use in Australasia. The next section summarises the scope and breadth of these guidelines as they relate to the need for a multifaceted psychological, environmental and biological approach to managing sexual deviance and its potential application to people with intellectual disability.
1. Available guidelines

Bone health and metabolic health for patients who are receiving androgen deprivation therapy

The first guidelines were sourced through a collaboration between the Endocrine Society of Australia, the Australian and New Zealand Bone and Mineral Society, and the Urological Society of Australia and New Zealand. They focus on recommendations around assessing and managing bone health and metabolic health for patients who are receiving androgen deprivation therapy for non-metastatic prostate cancer. They were published in the Medical Journal of Australia in March 2011 (Grossman et al. 2011). The paper outlines the application of a risks and benefits assessment in relation to their use, focusing on a number of possible adverse side effects arising from the medication, especially over the longer term.

In relation to bone health, the Grossman paper (2011) presents the case that bone-mineral density (BMD) is of particular concern. Results from prospective studies have demonstrated that the reduction in BMD starts very soon (within months) of commencing an anti-libidinal medication regimen, with rates of bone loss being some eight times higher than that found in the general population. Available evidence also suggests that while BMD loss is maximal in the first 12 months after commencing anti-libidinals, loss of BMD is still apparent in longer term use, with osteoporosis being a likely outcome of long-term use. The potential benefits from these guidelines focus on the recommended close monitoring of BMD, especially in the first 12 months of treatment, and the complications that arise when these pharmacological agents are administered over a prolonged period of time. These guidelines also lend significant weight to the argument of providing calcium supplements alongside anti-androgen medications.

World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for the biological treatment of paraphilias

These guidelines sought to help better inform clinicians in their decision making regarding the diagnosis and treatment of patients with paraphilia and, more broadly, improve the quality of care that is provided. The taskforce that undertook the extensive work included representatives from all five continents, including experts from France, Chile, Belgium, Canada and the United Kingdom. The taskforce reviewed all (English language) literature on anti-androgen treatments published in peer-reviewed journals and reviews published between 1969 and 2009 and included a more limited literature search regarding the use of selective serotonin reuptake inhibitors (SSRIs) between 1990 and 2009, again reviewing peer-reviewed outputs. Thibaut and colleagues (2010) note that a prior systematic review of SSRIs (Adi et al. 2002) identified only nine studies eligible for their meta-analysis. The paper by Adi and colleagues (2002) acknowledges methodological limitations in the case series studies included but concluded that, based on the available results, there was preliminary evidence of the potential value of SSRIs in treating sexual abusers.

The WFSBP guidelines considered the treatment and management of sexual paraphilias with pharmacological agents and how these could be supplemented with psychological interventions. To these ends, they reviewed all available English-language literature published over a 40-year period (1969–2009). Thibaut and colleagues (p. 606) point out that, ethically, a person may only be subjected to anti-androgen medications when all of the following six conditions have been met:
1. The individual has a paraphiliac disorder diagnosed by a psychiatrist after a detailed psychiatric exam.

2. The treatment addresses specific clinical signs, symptoms and behaviours, adapted to the individual's state of health.

3. Their condition represents a significant risk of serious harm to his health or to the physical or moral integrity of other persons.

4. That there are no less intrusive means of providing treatment available.

5. That the responsible psychiatrist agrees to inform the individual and receive their consent to take the responsibility for the indication of the treatment and for follow-up, including somatic aspects with support from an endocrinologist where necessary.

6. That the treatment is part of a written treatment plan, reviewed at appropriate intervals and revised as necessary.

The key points gleaned from here relate to the expert assessment of the paraphiliac disorder, the significant risk of serious harm, and the lack of appropriate, less intrusive, treatments. These points are not elaborated upon further or operationalised; for example, the specifics of what is meant by 'significant risk' and 'reviewed at appropriate intervals' are not detailed so as to enable a uniform approach to their use in practice.

The WFSBP guidelines specifically comment on observing severe side effects when these drugs are used. It further states that, based on research reported by Reilly and colleagues (2000) and Hill and colleagues (2003), anti-libidinal medications should not be used in the following cases/situations:

- non-consent
- puberty not completed (especially when bone growth is not completed)
- hepatocellular disease
- liver carcinoma
- diabetes mellitus
- severe hypertension
- carcinoma (except prostate carcinoma)
- pregnancy or breastfeeding
- previous thromboembolic disease
- cardiac or adrenal disease
- severe depressive disorder
- tuberculosis
- cachexia
- epilepsy
- psychosis
- allergy to cyproterone acetate
- drepanocytosis
- pituitary disease.
The WFSBP guidelines conclude that there are several pharmacological treatment options available; they note that these are in addition to psychological and other behavioural therapies and should be considered as part of a comprehensive treatment plan (p. 645). The authors assert that treatment choice should be determined by the following:

- the patient’s previous medical history
- the patient’s observance
- the intensity of the paraphiliac sexual behaviour
- the risk of sexual violence.

The guidelines conclude with a detailed algorithm clearly articulating a staged approach to the pharmacological treatment of paraphilias, based on Bradford (2000); these have been set out in Table 1.

Progression upwards step by step from level 1 through to level 6 approaches are based on finding that there are unsatisfactory results with treatment recommendations at lower levels. Of note, issues around compliance and risk are introduced beyond level 3, where a full dosage of anti-libidinal medications are first introduced alongside SSRIs (where additionally indicated) in the treatment plan.

### Table 1: The staged approach to the pharmacological treatment of paraphilias

<table>
<thead>
<tr>
<th>Level</th>
<th>Aim/Approach</th>
<th>Treatment</th>
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<tr>
<td>Level 1</td>
<td>- <strong>Aim:</strong> Control of paraphiliac sexual behaviour, compulsions and behaviours without impact on conventional sexual activity and on sexual desire</td>
<td>- Psychotherapy – preferably CBT if available due to low evidence base with other forms of therapy</td>
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<tr>
<td>Level 2</td>
<td>- <strong>Aim:</strong> Control of paraphiliac sexual behaviour, compulsions and behaviours with a moderate reduction of conventional sexual activity and on sexual desire</td>
<td>- SSRIs: increase dosage at the same level as prescribed in obsessive-compulsive disorder</td>
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<td></td>
<td>- May be used in all mild cases (‘hands off’ paraphilias with low risk of sexual violence such as exhibitionism without any risk of rape or paedophilia)</td>
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<tr>
<td></td>
<td>- No satisfactory results at level 1</td>
<td></td>
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<tr>
<td>Level 3</td>
<td>- <strong>Aim:</strong> Control of paraphiliac sexual behaviour, compulsions and behaviours with a moderate reduction of conventional sexual activity and on sexual desire</td>
<td>- Add low dosage of anti-androgen (for example, cyproterone acetate 50–100 mg/day) to SSRIs</td>
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<td></td>
<td>- ‘Hands on’ paraphilias with fondling but no penetration</td>
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<td></td>
<td>- Paraphilic sexual behaviour without sexual sadism</td>
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<tr>
<td></td>
<td>- No satisfactory results at level 2 after 4–6 weeks of SSRIs at higher dosages</td>
<td></td>
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<tr>
<td>Level</td>
<td>Aim/approach</td>
<td>Treatment</td>
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| Level 4| • **Aim**: Control of paraphiliac sexual behaviour, compulsions and behaviours with a substantial reduction of conventional sexual activity and on sexual desire  
  • Moderate and high risk of sexual violence (severe sexual paraphilias with more intrusive fondling with limited number of victims)  
  • No sexual sadism fantasies and/or behaviour (if present go to level 5)  
  • Compliant patient; if not, use IM or go to level 5  
  • No satisfactory results at level 3 | • First choice: full dosage of cyproterone acetate: oral, 200–300 mg per day or IM 200–400 mg once weekly or every 2 weeks; or use medroxyprogesterone acetate: 50–300 mg/day if cyproterone acetate not available  
  • If comorbidity with anxiety, depression or obsessive-compulsive symptoms, SSRIs might be associated with cyproterone acetate |
| Level 5| • **Aim**: Control of paraphiliac sexual behaviour, compulsions and behaviours with almost complete suppression of sexual desire and activity  
  • **High risk of sexual violence and severe paraphilias**  
  • Sexual sadism fantasies and/or behaviour or physical violence  
  • **No compliance at level 4**  
  • **No satisfactory results at level 4** | • Long-acting GnRH agonists  
  • Testosterone level measurements may be easily used to control GnRH agonist treatment observance if necessary  
  • Cyproterone acetate may be associated with GnRH agonist treatment (one week before and during the first month of GnRHa) to prevent a flare up effect and to control the risk of relapse risk of inappropriate sexual behaviour associated with the flare-up effect |
| Level 6| • **Aim**: Control of paraphiliac sexual behaviour, compulsions and behaviours with a complete suppression of conventional sexual desire and activity  
  • Most severe paraphilias (catastrophic cases of paraphilia, as operationalised in Bradford 2000, based on *Diagnostic and statistical manual of mental disorders* criteria)  
  • **No satisfactory results at level 5** | • Cyproterone acetate (50–200 mg/day orally or 200–400 mg once weekly or every 2 weeks IM; alternatively, medroxyprogesterone acetate (300–500 mg/week if cyproterone acetate not available) in addition to GnRH agonists  
  • SSRIs may also be added (although it is noted that there is no level of evidence available on their efficacy at this level) |

IM = intramuscular

Adapted from Thibaut et al. 2010

The WFSBP guidelines also stipulate details of a medical review process that should be used on a strict basis with all those on anti-libidinal medications (Table 2). Bradford (2000, p. 251) also notes that the treatment regimen proposed in the algorithm should only be used with a full understanding of the pharmacology of the medications.
Table 2: Medical review process for anti-libidinal medications

<table>
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<th>Timeframe</th>
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<tr>
<td>Every 1–3 months</td>
<td>• Paraphiliac and non-paraphiliac sexual activity and fantasies (nature, intensity and frequency)</td>
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<td>• Risk of sexual offending</td>
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<td>• Through self-reports of the patient</td>
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<td>Every 3–6 months</td>
<td>• Blood pressure</td>
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<td>• Weight</td>
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<td>• Depression and emotional disturbances</td>
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<td>• Risk of feminisation</td>
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<td>• Add blood cell counts, hepatocellular function if cyproterone acetate used</td>
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<tr>
<td>Every 6 months</td>
<td>• Fasting blood glucose levels</td>
</tr>
<tr>
<td></td>
<td>• Lipid profile</td>
</tr>
<tr>
<td></td>
<td>• Calcium and phosphate levels controlled</td>
</tr>
<tr>
<td>Every 24 months (or annually if at increased risk of osteoporosis or if aged over 50 years)</td>
<td>• Bone mass density</td>
</tr>
<tr>
<td></td>
<td>• Calcium, vitamin D or bisphosphonates must be prescribed in case of osteoporosis</td>
</tr>
<tr>
<td>Routine (no timeframe noted)</td>
<td>• Testosterone blood levels (in case of risk of breaks in therapy or masked testosterone supplementation)</td>
</tr>
</tbody>
</table>

Bradford (2000, p. 251) also notes a number of potentially influential mediating factors to consider that could contribute to a relapse of sexually inappropriate behaviours. These include: (1) abuse of substances, specifically alcohol but also non-prescription drugs; (2) mood disorders, specifically depression but any variation of mood disorder can disinhibit sexual behaviour; (3) noncompliance with pharmacological treatment; and (4) noncompliance with relapse prevention interventions.
2. Methodology

Experienced staff in the Office of Professional Practice identified a group of 24 people to participate in a Delphi-style consultation about their experiences with prescribing anti-libidinal medication to people with intellectual disability. The Delphi approach to consultation works well in situations where there is a lack of established evidence on a particular topic (see, for example, Linstone & Turoff 1975; Slade et al. 2008) and where bringing together the necessary breadth of expertise and opinion required to develop a satisfactory degree of consensus is impractical due to cost, time or geographical limitations. The consultation usually involves two or perhaps three rounds, whereby responses received from participants are synthesised and fed back for further, more focused questioning or clarification. One of the practical aspects of the method is consideration of the sometimes delicate balance of burden on participants (who are often asked to volunteer significant time) with estimated gains associated with elongating response timeframes to seek maximum inclusion and therefore breadth of participation.

The proposed sampling frame was deliberately broad to potentially capture the clinical, policy and legislative nuances of different jurisdictions with respect to the topic. As such, participants that were canvassed worked in the states of Victoria, Queensland, New South Wales, South Australia or Tasmania, or in New Zealand. Practitioners and prescribers were the primary target; their disciplines covered forensic psychiatry, nursing and psychology. Individuals in key policy roles were also invited to contribute. Of note, all 24 potential participants had either voiced a specific interest in having discussions on the topic area or were well known for their work with this population generally.

Potential participants were invited to participate in the consultation process by email by the authors, using an email contacts list provided by the Senior Practitioner – Disability, Office of Professional Practice. Procedurally, all potential participants were invited to participate up to three times over a period that spanned approximately three months. Due to busy working schedules and the voluntary nature of the request, as much flexibility as possible was allowed. This was to encourage participation to maximise responses and potential generalisability.

A standard invitation to participate was emailed to all potential participants. Participants were asked to provide responses on the following issues:

- the legal framework in their jurisdiction for prescribing anti-libidinal medication
- considerations and practicalities about how issues of capacity and consent are assessed with the target population
- details about any locally developed prescribing policies or protocols and the use of adjunct therapies.

Based on the direct relevance of, and level of detail available in, the WFSBP guidelines, these were selected as the most viable basis for treatment guidelines to be considered. Therefore, an electronic copy of these guidelines (from Thibaut et al. 2010) were also provided for the participants’ appraisal. Participants were asked to consider how suitable the guidelines would be in their jurisdiction and whether any modifications or other re-jigging would be required to make them suitable to be applied in their clinical/policy context.

Finally, participants were also asked to provide case examples of patients/situations they had encountered when working at this interface that typified the core issues of concern they faced clinically with this offender group and treatment options. A number of possible scenarios were suggested:

- where a person lacked the capacity of consent
- a person who was under the care of their jurisdiction’s Mental Health Act
- a person under the age of 16 whose parents objected to anti-libidinal medication
- any situations where they had faced challenges with therapies (biological, psychological or otherwise).
Participant responses were collated over a period of months. Responses were synthesised into a draft report then returned to all of the 24 participants who had originally been approached. The report was emailed to all potential participants, regardless of their participation in the original round of the consultation. This enabled those unable to respond initially to potentially still contribute to discussions. Participants were asked to consider the recommendations arising from the first round of the consultation and provide any further feedback and practical guidance regarding their utility. A strict two-week deadline was imposed on this second round of consultation. Responses were collated and incorporated in the final report.
3. Results

Legislative framework and commonality of use

Instances where a person had sexual behaviour that interfered with their ability to perform their usual daily activities (to the level recommended where anti-libidinal medication treatment may be indicated) were reportedly rare. As such, anti-libidinal medications were reported to be used uncommonly with the client group across the different jurisdictions, although some noted that they would not be against their broader usage where individual case presentations indicated their potential utility. A large proportion of those surveyed generally favoured the use of psychological approaches (mainly cognitive behavioural approaches) due, on the whole, to the reputed evidence base supporting the application and suitability of these psychotherapeutic approaches.

When considering instances where anti-libidinal medications had been prescribed in the different jurisdictions, most of the participants had used clinical guidelines that had been developed by staff at Forensicare, the statewide provider of forensic mental health services in Victoria (see the appendix). These clinical guidelines are very much based on, and make explicit reference to, the WFSBP guidelines circulated to potential participants in this consultation process.

Other participants reported being were generally aware of the WFSBP guidelines already and that they had referred to them in their own clinical decision making and review processes when individual clinical presentations had potentially indicated their applicability and utility as treatment options.

Indications for use of anti-libidinal treatments

Where there were indications for pharmacological treatment (see respondent-derived criteria in the box below), treatment priorities were consistent with those identified in the WFSBP guidelines. Respondents recommended that the client was first commenced on a serotonergic agent (SSRI) (for example, sertraline) at antidepressant-level doses. If there were subsequently contraindications to SSRIs or an inadequate response then a hormonal agent was recommended. It was also noted that SSRI treatment may continue in addition, if the client presented with comorbid depression. The choice of hormonal agent, cyproterone acetate or medroxyprogesterone acetate (MPA) was noted essentially to depend on likely compliance, as well as patient preference.

<table>
<thead>
<tr>
<th>Indications for anti-libidinal treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Compulsive fantasies with a proven inability to control their sexual arousal</td>
</tr>
<tr>
<td>• Predatory, violent sexual behaviours</td>
</tr>
<tr>
<td>• Sexual violence under institutional conditions</td>
</tr>
<tr>
<td>• Previous non-pharmacological treatment failures</td>
</tr>
<tr>
<td>• Patient is under considerable mental distress because of their uncontrollable drive</td>
</tr>
<tr>
<td>• Patients who are less capable of utilising cognitive therapies (major mental illness, ABI)</td>
</tr>
</tbody>
</table>

Recommendations regarding the existing WFSBP guidelines

When the participant’s recommendations were mapped with the WFSBP guidelines, there was significant overlap. All participants considered the guidelines helpful and informative and reported a need for, and that there would be benefit from, adopting such an approach routinely.

The consensus was that the WFSBP guidelines as they stood were essentially workable in the different jurisdictions; and indeed, as indicated by their responses, the majority of those who responded had either considered or used the guidelines as the basis for their practices in some format already. According to
the respondents the main challenge faced with incorporating the guidelines routinely was the degree to which the guidelines were readily translatable to the various legislative frameworks across both Australia and New Zealand.

One of the most significant barriers to implementing the guidelines and clinicians’ ability to adhere to them consistently related to the broader systemic issue of service provision. The current landscape across the different jurisdictions suggested a lack of suitably skilled and resourced services (for example, specialist behavioural services in Disability Services) in place to be able to offer, yet alone deliver, the necessary evidence-based psychotherapeutic interventions and, more fundamentally, providing the necessary environmental monitoring and support in the least restrictive setting. It was reported that the negative consequence of this specialist service shortfall was that available services often resort to using more coercive practices. For example, this included resorting to the use of more restrictive close supervision and the overuse and reliance on antipsychotics as a means of behaviour control.

The WFSBP guidelines, while broadly applicable, were considered to require an addendum to cater for the nuances of the Australasian context and, importantly, the variations in legislative frameworks. The experts made four key recommendations:

1. Careful consideration of the specific language and emphasis used throughout the guidelines is required so that they have direct and practical application across the different Australasian jurisdictions.

2. Consistency is key; as such, the terminology that is adopted has to be consistent with the legislation and therefore predicated around reducing and/or managing risk.

3. The guidelines require more specific information regarding the timing and frequency of clinical reviews regarding (1) any changes in sexual behaviour and functioning; (2) physical contradictions; and (3) reaffirming informed consent (note other recommendations arising in this report for further detail on this item). Practices reported in the different jurisdictions form the basis of some of those recommendations.

4. While the guidelines suggest that long-term outcomes after cessation of psychotherapeutic interventions show less positive outcomes, it was noted that this is not specific to this clinical population. What it does suggest, however, is the need for additional ‘booster’ sessions to help maintain psychotherapeutic treatment gains over time.

The issue of informed consent

Across all the jurisdictions from where participants responded, it was specifically noted that it was the responsibility of the medical practitioner to obtain the appropriate consents for prescribed medications. However, one of the main findings arising from the responses was their continued concern about the process and rigour adopted when seeking consent. Of particular note, current (and recent) practices witnessed by respondents suggested that best practice was not being followed and that patients were not participating fully (if at all) in the consent process. More specifically, several respondents reported significant concerns that some prescribers were misinterpreting compliance with the medication regimen for consent.

As such, it was recommended that the process of exploring the complex issues around capacity to consent and seeking informed consent will inevitably need to be ensured on a case-by-case basis, contingent on the combinations and complexities of the interventions that are being proposed in the treatment plan. Current practices in certain jurisdictions suggested a great deal of variability with respect to whether consent was sought on more than one occasion. The consensus from the respondents here was that consent was required from the patients and that it needed to be reaffirmed at every review meeting. These procedural issues are particularly important when considering the need for third-party consent, for example, the situation in Queensland where the Guardianship Tribunal is involved.
Outline of the proposed consent process

- The process of consent has to be thorough and transparent.
- There remains a need for simplified approaches to consent.
- It is recommended to use pictures and words presented in a narrative format.
- Use of oral checklist and score sheet (see below for an example).
- Consent must be reaffirmed at every review meeting.

Recommendations arising regarding consenting procedure

An adaption of the oral checklist and score sheet (see, for example, Lambrick & Glaser 2004) should be incorporated in the consenting procedure (see box for an example) and be performed by prescribers. Consistent with its original application, if any of the responses to the consent probe questions are judged to be incorrect then the person cannot be said to be providing informed consent.

It is recommended that this consent procedure is repeated and reaffirmed at every review. As noted by some respondents here, the process of consent should be seen as a continuing discussion between prescriber and patient until a firm decision has been made about the person’s understanding of the potential risks and benefits of taking these medications.

Outline for proposed oral checklist and associated score sheet

<table>
<thead>
<tr>
<th>Sample questions</th>
<th>Participant’s response (please record verbatim)</th>
<th>Example of a correct answer (list here)</th>
<th>Judgment of participant’s response as correct (tick box)</th>
<th>Judgment of participant’s response as incorrect (tick box)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you acknowledge that you have problems with illegal sexual behaviour? Can you give me an example?</td>
<td></td>
<td>‘Yes…’</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Do you know what side effects you might have from taking this medication?</td>
<td></td>
<td>‘It will reduce my sex drive’</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>‘I might gain weight/ experience low mood / feel sleepy / experience dizziness, headaches or rashes’</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Do you understand that blood test monitoring is required in order to adjust the dose properly?</td>
<td></td>
<td>‘Yes’</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Do you understand that this drug is not a contraceptive in males?</td>
<td></td>
<td>‘Yes’</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Have you discussed the risks and benefits of treatment with [insert anti-libidinal name], the possible alternative treatments and the risk of no treatment at all?</td>
<td></td>
<td>‘Yes’</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample questions</td>
<td>Participant’s response (please record verbatim)</td>
<td>Example of a correct answer (list here)</td>
<td>Judgment of participant’s response as correct (tick box)</td>
<td>Judgment of participant’s response as incorrect (tick box)</td>
</tr>
<tr>
<td>------------------</td>
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<td>-----------------------------------------</td>
<td>--------------------------------------------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>6. Do you understand that you may stop treatment at any time?</td>
<td>‘Yes’</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional questions here …</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total responses judged incorrect**

If any responses are judged to be incorrect, informed consent is not indicated.

**Witnessed (prescriber)**

| Name: | |
| Signature: | |
| Date: | |

**Signed (patient)**

| Name: | |
| Signature: | |
| Date: | |
4. Case examples

The following case examples seek to exemplify some of the practical complexities of working at this interface; examples are provided from three participating jurisdictions – Victoria, Queensland and New Zealand. The examples highlight instances where anti-libidinal medications have been prescribed to patients presenting with a range of risks and inappropriate sexual behaviours and highlight some positive and negative outcomes associated with the pharmacological treatment strategy. Of note, the respondents chose to present case examples where there had been positive benefit from their prescription, instances where treatment had been tried but stopped due to unpleasant/secondary side effects, and some of the longer term consequences associated with inadequate monitoring of the prescription of anti-libidinal medications on the health of the patients involved.

**Case examples 1 and 2** highlight examples where patients had some reported history of sexual offending previously but where no charges had been brought. In both cases the people had been prescribed anti-libidinal medications over a long period with questionable consent procedures in place and no detail about baseline monitoring of health and related conditions. Both patients have experienced deleterious effects on their quality of life (either through contraindications with other medications or, more problematically, contrary to their prescribed use under WFSBP guidelines with existing health conditions) from taking the medications but have remained on the anti-libidinal treatment regimen. **Case example 3** considers someone who is described in terms consistent with the target group (significant ongoing risk); the example raises important considerations about the veracity of the consenting procedures undertaken and also that the anti-libidinal medication treatment regimen was stopped due to unpleasant side effects (in this case depression). **Case example 4** considers a person for whom the recommended staged progression of interventions (from the WFSBP guidelines) has been followed due to a lack of reduction of sexually inappropriate behaviours (and escalation of some) and the ongoing consultations deemed necessary to consider informed consent. **Case example 5** depicts a long-term user of anti-libidinal medication and the benefits associated with initiating a regular monitoring structure, which have led to a reduction in dosage and improvements evidenced through combining this with psychotherapeutic interventions. Evidence of the long-term negative health consequences is also noted; however, it is not clear whether this is associated with a lack of close monitoring early in treatment or the long-term prescription of the medications. Also, of note, a suggestion that a more nuanced approach to determining consent identifies ongoing concerns about whether consent is actually informed consent. Last, **Case example 6** demonstrates a conflict between an expert opinion, guided by explicit referral to the WFSBP guidelines and those of other decision-makers and the knock-on detrimental effects on the individual and the risk management of that person. There were tangible benefits associated with anti-libidinal medications in this case, as part of a treatment plan. An additional challenge included here relates to challenges raised under a certain legislative framework (in this case where the Adult Guardian is involved) and differences of opinion this can lead to.

**Case 1: Victoria**

A blind 49-year-old male was previously alleged to have inappropriately sexually touched and masturbated in front of his young female half-sister, though there were no charges or other follow-up. He had psychotherapeutic involvement in 2005, with only limited success due to rigidity and concrete thinking around a paraphilic sense of entitlement and rigid cognitive distortions and so was immediately commenced on anti-androgen therapy. He has been on this ever since, with no baseline medical health monitoring, and the private psychiatrist wrote to inform him that he will have to be on anti-androgens for the rest of his life.

There are many protective factors (patient-related and environmental) that have been effectively managing any risk associated with this man, including his complete blindness, subsequent reliance on staff support for nearly all community access activities and his age. He is also prescribed an SSRI in
addition to the anti-androgen for managing arousal, without appropriate medical health review. The client reports that for a number of years he has had significant issues with difficulties masturbating to ejaculation and increased frustration and anxiety in relation to this. He may have significant difficulties with generalised anxiety, and this requires further assessment.

Case 2: Victoria

A 62-year-old male with a diagnosis of schizophrenia and with a history of sexualised behaviour towards children (no charges) was placed on anti-androgens in 1993 without baseline monitoring. His capacity to consent was questionable because he has a moderate intellectual disability. He currently has inoperable brain tumours and other complex health issues.

The private psychiatrist continues to prescribe anti-androgens despite the WFSBP guidelines stating that anti-androgens should not be prescribed in cases of carcinoma (except prostate carcinoma, which he does not have). Again, given his age and support needs, the ongoing use of anti-androgens needs to be questioned, including its exacerbations of the existing carcinoma and other side effects (specifically in relation to bone density) that may further affect his quality of life in the context of terminal illness, disability and age-related factors.

Case 3: New Zealand

A 30-year-old male with an established mild intellectual disability was being held under the Mental Health Act 1992 following a conviction for a burglary with a high level of sexual motivation. His offending predated the introduction of the Intellectual Disability (Compulsory Care and Rehabilitation) Act 2003 in New Zealand. He has a history of a sexual homicide and a long history of sexualised behaviour including public masturbation, self-harm to his genitals and sexually inappropriate interests including power tools, public masturbation and fantasies of rape and murder.

In the months leading up to the use of anti-androgen medication, he had been masturbating about five times a day and displaying persistent sexually inappropriate behaviour on the inpatient unit. This including exposing himself, public masturbation, touching of female staff and patients and sexually inappropriate remarks. Given his history of significant sexual offending and persisting evidence of a high level of libido coupled with sexually inappropriate fantasies, his treating psychiatrist requested a second opinion under s. 59 of the Mental Health Act for the use of cyproterone acetate. The assessing psychiatrist providing the second opinion noted the patient’s high level of sexual arousal and active fantasies.

He had been placed under the Mental Health Act on the basis of having disorders of cognition and volition related to his sexual deviancy and sexual offending as well as other difficulties. Accordingly the psychiatrist providing the second opinion considered that the treatment with anti-libidinal medication was within the ambit of the Mental Health Act. He also found that the patient consented to the use of anti-libidinals, although he didn’t explore his capacity further other than noting that he had some insight and understanding of the purpose of the medication. He was commenced on cyproterone acetate, but the medication was stopped three months later because of secondary depression.

Case 4: New Zealand

In 2005 a 53-year-old man was convicted of raping an acquaintance. He had been tested and confirmed to have a mild intellectual disability and assessed by a forensic psychiatrist who found that he was unfit to be tried. He had had a disturbed childhood and had been the victim of serious institutional sexual abuse. He had been hospitalised in a psychiatric hospital for 20 years. He suffers from epilepsy. From the time of his release from hospital in the early 1990s there was a high level of concern about his sexual behaviour, particularly his use of pornography and frequent sexual overtures to women. Despite this he was living independently with support in the community.
Following his conviction he was placed under the Intellectual Disability (Compulsory Care and Rehabilitation) Act on a hybrid order with a sentence and commenced on a program of rehabilitation within the secure Intellectual Disability Service. This included group and individual work in a sexual offender treatment program specifically designed for people with intellectual disability. At times he seemed to make progress; however, recurrently he would show signs of relapse, manifested particularly by oppositional and angry behaviour. Although he denied ongoing sexual urges, he reported frequently that he was innocent of the index offence, displayed no victim empathy and continued to manifest sexualised behaviours. These included occasional displays of his genitals, masturbating in places he may be readily be seen and he began collecting sex line phone numbers and numbers of escorts from personal columns to satisfy his sexual behaviour.

Attempts were made to engage him in individual psychological therapy. He heavily sexualised his relationship with the female psychologist with active fantasies of sex with her and others. Continued concern about his ongoing risk of sexual offending was expressed by those engaged in his treatment in the sexual offender treatment program. Given the seriousness of his index offending, and the evidence of persisting high risk of further similar offending, he was judged to be a suitable candidate for cyproterone acetate. At this point discussion occurred with his parents, who supported him using this medication, rather than attempting to seek a second opinion under the Act. Although he is intellectually disabled he has reasonable language skills and a sufficient level of cognitive functioning to grasp the implications and the basics of the reasons for using anti-libidinals, and their potential side effects. He is therefore considered capable of consenting. The process of obtaining consent continues.

Case 5: Victoria

A 49-year-old male with a mild intellectual disability and an extensive history of institutional placement since the age of seven was a victim of sexual abuse from a staff member and residents at the institution. He lived independently between 1982 and 1998, and during this period committed a number of sexual offences including offences against a person under 10 years of age, multiple accounts of indecent assault and soliciting for sexual purposes. He was placed in an intensive residential treatment program from 1998 to 2007. He was prescribed anti-libidinal medication prior to 1998, perhaps as far back as 1988. There was no evidence of baseline testing or monitoring until 2008, although there was regular screening for testosterone levels.

In 2007 he transitioned to a less intensive community-based group home where his treatment program was maintained. In 2008 he suffered a fracture of his left hip and from that time began treatment for poor bone densitometry. During this period he continued to be treated for paedophilia (sexually attracted to males, nonexclusive type), being on 450 mg Depo Provera IM on a fortnightly basis. He commenced reductions of Depo Provera from 2009 and has been reduced to 100 mg. He continues to live in the group home and continues to participate in his treatment maintenance program.

This case has had a successful outcome in the sense that he moved to a far less restrictive environment and maintained this community-based placement. He engages in meaningful daytime activities, undertakes periods of unsupervised community access and regularly stays with family members. He underwent an intensive modified CBT-based sex offender treatment program over a period of approximately five years, and the subsequent relapse prevention plan continues to be maintained. While the long-term prescription of anti-libidinal medication in conjunction with psychological treatment has been of significant positive benefit, the longer term health outcomes and lack of monitoring of his health status in earlier years has contributed to significant negative outcomes for him. Over recent years there have been regular informed consent processes undertaken with him; however, he did not pass an appropriate informed consent oral checklist process for a research study.
Case 6: Queensland

John is a 30-year-old, single Aboriginal man with mild intellectual impairment. He was referred for a forensic opinion in May 2009. He had been on a forensic order under the Mental Health Act 2000 (Qld) since April that year, on the grounds of unfitness to plead on a 2005 charge of indecent dealing with an 11-year-old boy. This involved squeezing the covered genitals of the son of his carer while on an outing at the beach.

John had a prior history of sexual assaults. His first sexual offence was an aggravated assault of a sexual nature involving pressing his erect penis against the unclothed groin of a 10-year-old boy in a toilet cubicle. He also had convictions for non-sexual offences (wilful damage, stealing and unlawful use of a motor vehicle). As a consequence of his intellectual disability he had a low frustration tolerance and a propensity for aggressive acting out.

John was ‘watched all the time’ on a rural property. Past carers had voiced their concerns about his sexual behaviours; one reported that during outings she noticed John peering at male children. She referred to a number of incidents such as John putting his hands up the shorts of a 10-year-old boy at a festival, sneaking out of the house in the early hours and peeping through a five-year-old male neighbour’s window while masturbating, entering the men’s toilet while his carer was distracted and holding the toilet door shut to prevent a young boy leaving.

John was described as ‘moody’ but had no diagnosable mental disorder. Pharmacological approaches to his behavioural problems had included chlorpromazine and thioridazine (poorly tolerated and limited efficacy), and the current regimen of risperidone and fluoxetine. He was said to be less aggressive on risperidone, but there was no evidence this medication had suppressed his sexual behaviours. There was no significant history of substance abuse.

John was illiterate and under a guardianship order. Past psychological testing had shown ‘significant limitations in his planning and decision-making abilities, and his capacity to speculate the outcome of his actions.’ Little was known of John’s own childhood, but there were references to being sexually victimised at around the age of eight while in the care of an uncle. John favoured television shows depicting male children and adolescents and he also accessed pornography (magazines and DVDs) from a former resident, but there had been no censorship of this material because it was regarded as ‘private’. His carers had seen the covers of some of these magazines, which depicted young men. John viewed this material in his room. John did not have any other contact with children. John had no known physical health issues.

The forensic assessment concluded that there was no major mental illness. There was some indication that his angry outbursts had diminished on risperidone though other factors, particularly environmental changes, may have contributed to his improved manageability. There was no clear support for the efficacy of fluoxetine. The interview, criminal record and observations of carers provided compelling support for a diagnosis of paraphilia (paedophilia). His predominant source of sexual interest and arousal based on official and unofficial reports appeared to be male children, ranging in age from five to 12 years. He had repeatedly acted on his urges from the age of 16, whenever circumstances made it possible. His offences had a typically opportunistic pattern, but they had also been characterised by grooming behaviours and efforts to conceal his activities. He had consistently denied his offending, though in more recent times he had established sufficient trust in his male carer and Disability Services psychologist to acknowledge some problems.

Past attempts to control John’s sexual urges through psychological counselling, antipsychotic agents and serotonergic antidepressants had not ameliorated the problem. Given his significant offending history, the high risk of sexual reoffending, entrenched cognitive distortions and his poor executive functioning, it was considered that psychological approaches alone were unlikely to reduce this risk and that John’s optimal management should incorporate psychological, environmental and biological components, namely hormonal anti-libidinal medication. The treating mental health service and GP accepted this
advice and the extensive guidelines provided. Relevant information was provided to John's guardian, seeking his consent to begin treatment (cyproterone acetate). The treatment was also explained to John in simple terms and he was amenable, on the basis that he might in future be able to cease his other medication. It was emphasised that psychological counselling should continue in conjunction with biological therapy, and that the current environmental controls be maintained. Since John was unlikely to reliably self-report his sexual thoughts, urges and behaviours, his psychologist agreed to develop a suitable rating scale to enable his carers to effectively monitor the efficacy of treatment. Baseline blood tests and physical examination were conducted in June 2009, in anticipation of commencing cyproterone acetate.

Disability Services and the Adult Guardian didn’t support anti-androgen treatment for John. An application was made to appoint a guardian for a restrictive practice, and that guardian took months to respond to further requests. Protracted hearings ensued. During this time, the mental health service applied to the Mental Health Review Tribunal (MHRT) to revoke the forensic order, arguing that the mental health service was not providing any additional assistance and that, in the absence of hormone treatment, his behavioural problems could continue to be managed by Disability Services. Unfortunately, there were now other residents living with John (including teenage boys), and he was absconding frequently from the property and having to be readmitted under police escort to hospital. The MHRT upheld the forensic order on the basis that Disability Services lacked the resources to manage the risk.

The Adult Guardian finally approved anti-androgen treatment in 2011. All baseline tests were repeated and the GP fully apprised. Since achieving effective levels of cyproterone acetate John has reported a reduction in sexual thoughts, and there has been an observable decrease in his aggression and propensity to abscond. He has retained some sexual functioning. He engaged in counselling with a psychologist who specialises in sexual deviance, but funding for this evaporated. A recent assessment by a psychiatrist for Disability Services, while John was stable on anti-androgens, opined that there was no evidence that John was benefiting from hormonal treatment and that the cyproterone acetate should be ceased. The Adult Guardian has accepted this opinion, although both the treating mental health service and expert psychiatrist have made contrary submissions. Disability Services continue to stress that it is not their responsibility to manage risk.

John is now on a slow taper of cyproterone acetate – not necessary, but it will hopefully provide ample opportunity to detect any lapses. In the meantime, John continues to live in a restricted setting, on risperidone, and faces the prospect of renewed absconding and further readmissions to the high dependency unit.
5. Summary and recommendations arising

Despite continued vocalisations about the need for controlled studies with transparent inclusion and exclusion criteria, and more robust, long-term follow-up, such rigorous methodologies remain an ideal as opposed to a reality, particularly with intellectually disabled sex offenders. In such instances, and as recommended by Ashman and Duggan (2008) and Dennis and colleagues (2012), we are forced to consider what evidence there is that is available.

A review of this evidence finds two distinctly polarised standpoints. On one hand, there is a steadfast and accumulating evidence base to suggest that anti-libidinal medications should not be prescribed, especially in instances where informed consent cannot be established, because of the potentially significant and harmful side effects that can be experienced and the lack of ability of some of those affected to communicate their distress and/or discomfort. One the other hand, there are a number of case studies that, taken altogether, suggest that anti-libidinal medications have a role to play in treating and managing a small proportion of people with high-risk sexually inappropriate behaviours.

Authors assert that because these offenders do not in any way represent a homogenous group, there is little if any chance that a one-size-fits-all approach will work in practice, hence, perhaps, the divergent findings found in the available literature. The greatest successes that have been reported in the literature regarding the use of anti-libidinal medications have consistently been found in situations where the person receives the pharmacological intervention in conjunction with psychotherapeutic interventions, utilised among those who are motivated to change.

The reported rarity of use of anti-libidinal medications in the Australasian context points firstly to the size and focus of the potential target group of interest here – namely those people that Bradford (2000) referred to as the most ‘seriously sexually inappropriate’. These individuals are characterised as those who are at high risk of sexual offending and who pose an immediate and significant ongoing risk to the community.

There was some suggestion from the respondents surveyed here that the uncommon use of anti-libidinal medications with intellectually disabled sex offenders may actually reflect a broader systematic approach whereby the potential utility of these treatments with some offenders are under-utilised in favour of resorting to more restrictive environmental management strategies. As such, the vexed question about whether to consider trialling anti-libidinal medications with this niche target population essentially boils down to balancing the risks and benefits of two options: (1) a decision to not prescribe anti-libidinal medications, leading to a sustained period where liberty is deprived through containment and management in more coercive, restrictive environments; or (2) prescribing anti-libidinal medications and then traversing the possibility of deleterious and distinctly unpleasant side effects but potentially being able to have greater liberty and freedom of movement. What is clear is that informed consent is of paramount and central importance whichever option is ultimately decided.

The WFSBP guidelines define the only appropriate target group for anti-libidinal medications as those with paraphilias that are ‘characterised by intense and frequent inappropriate sexual desire and sexual arousal which highly predispose the [client] to severe paraphilic behaviour (such as paedophilia or serial rapes)’. The respondents surveyed here suggest more of a mixed presentation among those they have encountered who are prescribed these medications. They highlight individual cases where the use of anti-libidinal medications has had positive benefit as well as cases where the side effects and/or poor health monitoring and review have been highly harmful to the patients involved. If hormonal treatment is to be considered as a treatment option, best practice indicates that treatment should be closely supervised by clinicians with requisite expertise and, most importantly, that treatment should be administered in conjunction with psychotherapeutic interventions. This leads to the following recommendations.
Recommendations

- Anti-libidinal medications should only be considered for the small population of sexual offenders for whom psychological therapies have been thoroughly tried and tested but have not worked and where the risk of further offending presented by the person is unacceptably high.

- A person’s risk of sexually violent offending should be ascertained through thorough assessment, by trained clinicians, using current gold standard sexual violence risk assessment tools. At the time of writing these would arguably include the SVR-20 and Risk of sexual violence protocol (RSVP). These risk assessments should form a triangulation with self-report and collateral information to provide the most complete assessment of the person’s risk.

- There needs to be further expert discussion and consultation about the perceived need to prescribe these medications to people with intellectual disabilities who have not offended but who may be at risk of offending. This discussion will necessarily be guided by robust structured professional judgement assessments of risk but needs to include a detailed consideration that clearly differentiates inappropriate sexual behaviour from the expression of what amounts to normal sexuality.

- Where anti-libidinal medications are considered as a treatment option, this should only be through engaging a specialist forensic psychiatrist and after detailed expert assessment. The professional with this expertise should provide ongoing monitoring of the pharmacological treatment of the person’s physical and mental health as well as capturing the potentially more nuanced changes in attitudinal and behavioural change. All of these provide some indication of the impact of the treatment on the person and of their risk.

- There needs to be agreement on the need for regular follow-up and expert clinical review of the treatment response and side effects with an overarching decision made with respect to whether benefits of continuing with the anti-libidinal medication regimen and dose outweigh the risks associated with their continued use.

- The use of anti-libidinal treatments should only be considered as part of a multifaceted treatment and support plan that comprises psychological, environmental and biological components.

- Informed consent is paramount and should be reaffirmed at every review meeting. An oral checklist approach is favoured and can be readily adapted to the specifics of the multifaceted treatment plan being put in place. Case examples provided suggest that the consenting process, and judgements of capacity, may necessarily take place over a number of meetings over time.

- Medical monitoring (testosterone, body mass index, blood pressure, luteinising hormone, full blood exam, fasting glucose and breast examination) should be at least every six months, with at least biannual measurements of bone mass density. Much more regular testing is required where clinically indicated through the presence of measurable/reported side effects (for example, possible indicators of jaundice or diabetes).

- Where anti-libidinal medications are prescribed, additional calcium and vitamin D supplements should be prescribed routinely.

- While not specifically recommended by the experts, it is further proposed that prescribers in each jurisdiction sign a memorandum of understanding regarding adherence to the guidelines. Appended to this should be a copy of the guideline with any jurisdiction-specific considerations.
Appendix: Forensicare clinical guidelines for prescription and monitoring of anti-libidinal medication

Made available by Dr Danny Sullivan, 23 January 2013

Background
These guidelines have been developed by reference to the recent 2010 World Federation of Societies of Biological Psychiatry Guidelines for the biological treatment of paraphilias.

Rationale
Anti-libidinal medications may reduce sexual drive effectively. In populations of those at risk of sexual offending, prescription is premised upon the clinical assessment that offending is driven by high libido or compulsive behaviour and it may decrease the level of distress of the paraphilic subject or is of high risk and likelihood of significant harm to others.

Consent
Specific attention must be given to informed consent, covering risks and benefits, and noting that except for cyproterone, these are off-label indications. A signed consent form should be placed in the file. There will be rare situations in which anti-libidinal medications are prescribed to patients without consent; a reason for this should be clearly stated and will require some form of proxy consent or legal justification.

General principles of prescribing
The least intrusive treatment should be given priority.
Information about potential cardiac side effects should be forwarded to the general practitioner.
It is recommended that these medications are prescribed in conjunction with engagement in psychological treatment.
All patients prescribed anti-libidinal medications should be discussed regularly at the PBP quarterly anti-libidinal peer review.
Anti-androgen medications and GnRH analogues must not be used before puberty and bone growth are completed.
All patients (unless contraindicated) should be commenced on calcium and vitamin D supplements, for example, Ostelin vitamin D plus calcium, and all patients should be advised to abstain from smoking and excessive alcohol use. In some patients, bisphosphonate prescription may be warranted. If uncertain, endocrinology consultation should be sought.
Consideration should be made of an initial trial of SSRI, especially in:
• Non-high-risk cases
• adolescents
• those with depression, anxiety or obsessive features.
The development of adverse effects may not warrant discontinuation, but in individual cases reconsideration of risks and benefits is indicated, along with increased monitoring and, if necessary, specialist or GP consultation for advice.
Duration of treatment
According to the great majority of authors, a minimal duration of treatment of three to five years for severe paraphilia with a high risk of sexual violence is necessary. Hormonal treatment must not be abruptly stopped. In cases of mild paraphilia, a treatment of at least two years might be used, after which the patient must be carefully followed up in case of treatment interruption. Treatment must be resumed in cases of recurrence of paraphilic sexual behaviour.

Dosages
For cyproterone acetate (CPA, cyproterone acetate)
- 50 mg BD PO – increase as indicated to a maximum of 300 mg PO daily
For leuprorelin acetate (LEU, Lucrin)
- 3.75–7.5 mg IMI monthly, 11.5 mg IMI three-monthly – concomitant treatment with CPA 100 mg daily is essential for the first two to three weeks, which should be supervised or monitored closely (to prevent testosterone ‘flare’)
For medroxyprogesterone acetate (MPA, Depo Provera)
- 150 mg IMI fortnightly – increase as indicated to a maximum of 500 mg IMI fortnightly

Baseline monitoring
Consider history of epilepsy, diabetes, severe hypertension, hepatic or renal disease, prior fractures, active pituitary pathology, family and personal history of cardiovascular events or osteoporosis, psychosis, severe depression, alcohol and tobacco consumption or allergy to hormonal treatment.
- Weight, BP, ECG, fasting glucose and lipid profile
- DEXA scan (bone densitometry)
- FBE, CUE, LFT
- Clotting profile
- CaPO4, vitamin D
- Serum testosterone, LH, FSH, prolactin

Further monitoring
- FBE, CUE, LFT, testosterone monthly for first four months, then every six months
- Weight, BP, glucose, lipid profile, at three months
- Weight, BP, glucose, lipid profile, CaPO4, FSH, LH every six months
- DEXA scan every two years (yearly with MPA, if over 50 or if of concern)

Monitor for risk of sexual offending, paraphilic and non-paraphilic sexual activity and fantasies (nature, intensity and frequency), emergence of depressive symptoms, emotional disturbance, cardiac symptoms, thromboembolism, feminisation effects for example breast changes every one to three months.
References


