

# Modafinil in sports: ethical considerations

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Performance enhancing agents are prohibited in athletic competition so that only athletic skills can determine outcomes. Modafinil is a novel non-addicting psychostimulant approved for treatment of narcolepsy. Does its use, especially for medical indications, violate the Olympic Movement Anti-Doping Code? This is discussed with reference to a current high profile case.

The foundation of amateur athletics is the Olympic triad: (a) creed, (b) oath, and (c) motto. (a) "The most important thing in the Olympic Games is not to win but to take part, just as the most important thing in life is not the triumph but the struggle. The essential thing is not to have conquered but to have fought well."<sup>1</sup> (b) In the 2000 Olympics, the reference to non-use of drugs was added to the Olympic oath. "In the name of all competitors, I promise we shall take part in these Olympic Games, respecting and abiding by the rules which govern them, committing ourselves to a sport without doping and without drugs, in the spirit of true sportsmanship, for the glory of sport and the honor of our teams."<sup>2</sup> (c) The Olympic motto is: "citius, altius, fortius" or "swifter, higher, stronger."<sup>3</sup>

Amateur athletic competition must occur on an even playing field. To that end, performance enhancing agents are prohibited in amateur athletic competition so that only athletic skills can determine outcomes. Although performance enhancing agents, especially amphetamines and anabolic steroids, were used throughout the past century by Olympic athletes, it was not until 1967 that the International Olympic Committee Medical Commission listed specific drugs as banned substances, and athletes were disqualified for taking such agents.<sup>4</sup> Yet the rules are specific, if a drug is not listed as a banned substance, the athlete should not and cannot be disqualified for having taken such agent. This brings one to the crux of the problem in athletics—the spirit and letter of the law. The letter of the law is exact, the spirit of the law is much broader. It is no longer a question of the pleasure of competition, or the glory of athletic victory, but now endorsements/appearances/results are major economic factors. When athletes were purely amateurs, there was a greater willingness to accept the spirit of the law. When athletes and coaches realised that a non-banned substance would result in performance enhancement, these were not always used. But not all athletes, coaches, or countries were honest. Perhaps the greatest stain on amateur athletics and sports physician credibility was the national "doping" programme developed by East Germany,

which included unethical experimentation on minors and the specific research intent of finding means of administration of substances that would evade international control.<sup>5–6</sup> The pervasive use of doping agents led to an anti-doping hot line in Sweden which clearly defined this to be a public health problem.<sup>7</sup>

This use of non-banned substances resulted in the inclusion of the phrase "related substance" to the specific banned drug list (stimulants; narcotics; anabolic agents; diuretics; peptide hormones, analogues and mimetics; masking agents;  $\beta$  blockers) in the Olympic Movement Anti-Doping Code (OMAC).<sup>8,9</sup> Further, the Olympic Charter (effective 4 July 2003) dictates that all athletes, coaches, trainers, and officials will "comply with the provisions of the Olympic Charter regarding the World Anti-Doping Code (Rules 45 and 48)."<sup>10</sup> But is the use of this phrase always appropriate? Further, if a "related substance" is used to treat a medical condition, would it be ethical to disqualify an athlete? The novel psychostimulant, modafinil, is a case in point.

Modafinil has shown efficacy in, and is FDA approved for, treating daytime sleepiness associated with narcolepsy, sleep apnoea/hypopnoea syndrome, and shift work sleep disorder.<sup>11–13</sup> Additional off-label uses include treatment of sedation and fatigue in depression,<sup>14,15</sup> multiple sclerosis,<sup>16</sup> myotonic dystrophy,<sup>17</sup> opioid induced sleepiness,<sup>18</sup> and Parkinson's disease.<sup>19</sup> Further, modafinil has been used to treat spastic cerebral palsy,<sup>20</sup> attention deficit hyperactivity disorder,<sup>21</sup> and depression in monotherapy.<sup>22</sup> Cognitive enhancement has been noted with modafinil in healthy volunteers.<sup>23</sup> Neuroprotective qualities have been identified in mptp-animal-Parkinson models.<sup>24</sup> The use of modafinil in reducing food intake has also been studied, with a role in treating obesity suggested.<sup>25</sup>

Unlike dextroamphetamine and methylphenidate, there does not appear to be a risk of abuse associated with modafinil.<sup>26,27</sup> Modafinil is a suggested treatment for amphetamine and cocaine dependence.<sup>28,29</sup>

Further, unlike dextroamphetamine and methylphenidate, the c-fos expression is limited mainly to the anterior hypothalamic nucleus, adjacent areas, and the orexin neurones.<sup>30–32</sup> Although the specific mechanism of action for modafinil is unknown, alterations in orexin,  $\gamma$  aminobutyric acid (GABA) transmission and GABA/glutamate balance have been implicated.<sup>33–36</sup>

Does use of modafinil, especially for medical indications, violate the OMAC?

## CASE

In the 2003 World Track and Field Championships, a female elite sprinter (Kelli

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White) won a rare sprint double (100 m/200 m).<sup>37</sup> She tested positive for modafinil after her 100 m victory; however, she tested negative after her 200 m victory.<sup>38–39</sup> As the existence of a positive urine for modafinil was known before the 4×100 m relay, she withdrew from that event in order that any potential sanction she might receive would not affect her team.<sup>40</sup> This sprinter later informed the International Association of Athletics Federations (IAAF) that she was prescribed modafinil for the treatment of narcolepsy by her personal doctor and that she has a positive family history of this illness.<sup>41</sup> The IAAF reviewed her case, felt that modafinil fell under the umbrella phrase of “related substances” for stimulants, did not accept her explanation, and referred the case onward to the member federation, USA Track and Field (USATF).<sup>42–43</sup> If the USATF confirms a doping offence, then this athlete will be disqualified from the competition, stripped of her two gold medals, and publicly warned.<sup>42–43</sup>

## DISCUSSION

The present case poses multiple questions. Firstly, should modafinil be considered a psychostimulant? Secondly, if it is a psychostimulant, and yet is required to treat a medical condition, should the athlete be disqualified? Thirdly, how should one verify the alleged medical diagnosis? Fourthly, what must the athlete do in order to maintain eligibility to compete when on a “banned substance?” Fifthly, should the punishments be specific or should they be tailored to specific situations? Sixthly, are we witnessing further doping scandals?

Modafinil is not a classic psychostimulant as noted by its c-fos expression, mechanisms of action, minimal abuse potential, and its use to treat amphetamine abuse.<sup>26–36</sup> Its pharmacological profile is clearly different from standard psychostimulants.<sup>44</sup> Nonetheless, if a psychostimulant is defined as improving cognitive functioning, wakefulness, and energy, then modafinil meets such criteria.<sup>23–45–46</sup> However, this may be too broad a definition—for example, antidepressants improve cognitive functioning, wakefulness, and energy in depressed patients. It is worthwhile noting that the narcolepsy literature differentiates psychostimulants from modafinil.<sup>47</sup> As such, the inclusion of modafinil by OMAC-Ia (stimulants) as a “related substance” remains unclear.

However, if the athlete is using modafinil to treat a medical condition, then disqualification for having taken such would not appear, on initial evaluation, to be ethical. To not allow the use of this agent, would mean that the athlete is functioning at a handicap, for modafinil has been shown to improve fatigue associated with narcolepsy.<sup>48</sup> As such, the athlete should not be disqualified. Of import is how much of this agent is necessary to effectively treat the medical condition. For if more than the required dosage were taken, would it mean that the athlete is in fact taking a performance enhancing agent beyond therapeutic treatment? This would require expert medical opinions.

There is no clear gold standard diagnosis for narcolepsy. Narcolepsy is clinically characterised by excessive daytime sleeping; polysomnography reveals the presence of sleep onset rapid eye movement periods during the multiple sleep latency test.<sup>47–49</sup> Recent research has shown the Epworth sleepiness scale (ESS) to be more discriminative than the multiple sleep latency test.<sup>50</sup> Narcolepsy is a complex genetic disorder; family history of this condition, as was asserted in this case, may assist in diagnosis.<sup>47–51</sup> As such, proof of this medical condition should be based on clinical presentation. ESS, sleep studies, and HLA typing are diagnostic tools used to confirm this diagnosis.<sup>47–49–50–52</sup>

The World Anti-doping Code (WADC) clearly addresses prohibited substances and exemptions.<sup>53</sup> WADC defines potential inclusion in the prohibited substance: “medical or other scientific evidence, pharmacologic effect or experience

that the substance or method has the potential to enhance or enhances sports performance” (4.3.1.1, p15).<sup>53</sup> In addition, “WADA shall adopt an International Standard for the process of granting therapeutic use exemptions” (4.4, p17).<sup>53</sup> However, the key is the comment to 4.4 which states: “Athletes who use medically prescribed Prohibited Substances may be subject to sanctioning unless they have previously obtained a therapeutic use exemption” (4.4 Comment, p17).<sup>53</sup> WADA further authorises the international federations (in the case of track and field this would be the IAAF) for granting or denying exemptions for international level athletes.<sup>53–55</sup> IAAF clearly defines Control of Drug Abuse (Division III (Rules 55–61, pp 82–91))<sup>54</sup> and the appropriate procedure to obtain an exemption (Section 5, p17).<sup>55</sup> In this case, the athlete did not obtain the requisite exemption nor did she list modafinil as a medication she had taken on the urine samples tested.

Although fairness is sought in doping cases, a strict liability rule is usually applied. Perhaps the most telling case is that of a 16 year old Romanian gymnast who was stripped of the Sydney 2000 Olympic Games women’s all-around gold medal when she tested positive for pseudoephedrine after taking OTC cold tablets.<sup>56</sup> Although she was unaware of the presence of a prohibited substance (given by her team doctor), and although it made her dizzy and was not a performance enhancing agent, the Court of Arbitration for Sport confirmed that the athlete had committed a doping offence.<sup>56</sup> Summary statements included: “This is what we call the strict liability rule—the consequences being the automatic disqualification as a matter of law and fairness to all other athletes. The fact that the drug may not have enhanced performance and the reliance on the team doctor are irrelevant.”<sup>56</sup> This gymnast won and was allowed to keep her individual vault silver medal; the finals for this event took place after the individual all-around disqualification. This is consistent with the current WADC: “If the Athlete establishes that he or she bears No Fault or Negligence for the violation, the Athlete’s individual results in the other Competitions shall not be disqualified unless the Athlete’s results in Competition other than the Competition in which the anti-doping rule violation occurred were likely to have been affected by the Athlete’s anti-doping rule violation” (10.1.1, p 26).<sup>53</sup> This poses an ambiguity in the current situation—Kelli White was negligent for not filing an exemption; however, she was not negligent for taking a therapeutic agent for treatment of a medical condition. As such, it would appear to indicate that she should be disqualified from the 100 m but not the 200 m where she tested negative.

The prevalence of narcolepsy is only 0.02–0.05% in the United States.<sup>47</sup> To have an elite athlete with narcolepsy would be rare; however, when the 2003 US Track and Field Championship urines were retested, a total of six athletes were reported positive for modafinil during 2003.<sup>57</sup> Although Kelli White is the only athlete to state that she has narcolepsy, it is not surprising that the IAAF has scoffed at “a narcolepsy epidemic.”<sup>58</sup> Effective from 2004, modafinil has been added to the WADC banned list.<sup>59</sup> Further, four US athletes tested positive for the new designer steroid tetrahydrogestrinone.<sup>60–61</sup> USATF has responded to these positive test results with proposed strict sanctions for athletes and coaches, significant financial fines, and lifetime bans for steroid offences.<sup>62</sup>

## CONCLUSION

Whether modafinil is a “related substance” to stimulants remains unclear, especially in the domain of an athlete with a medical condition such as narcolepsy. From an ethical perspective, an athlete with a medical diagnosis should not be prevented from taking the appropriate medication, even if it is on the banned list. In this case, the critical issue is that the athlete did not request an exemption nor did she list this medication as having been taken. From a strict

## Key points

- Amateur athletics is premised on competition performed on an even playing field.
- Doping has led to the need for sanctions and specific anti-doping codes.
- Athletes with medical illnesses can compete when treated with banned or "related" substances if a medical exemption is obtained.
- The use of modafinil in athletics is addressed with the need to obtain a medical exemption and to have the appropriate diagnostic evaluation.
- Clinicians must be aware of those therapeutics that are banned or "related substances," treat the athlete accordingly, and assist the athlete in obtaining medical exemptions.

interpretation, sanctions apply, but it is felt most appropriate that these be limited to disqualification from the 100 m. However, the existence of at least five more elite athletes with positive modafinil tests raises a serious red flag. Research studies are indicated to determine if modafinil is a performance enhancing agent. All athletes using modafinil should properly ask for exemptions, list this as a drug being taken, and have the appropriate medical diagnosis with supportive diagnostic procedures (sleep study, ESS). Amateur athletics, once the purest form of physical expression, should not be debased by doping; nor should medically ill athletes be prevented from competing on the same even playing field by being denied appropriate treatment.

Competing interests: none declared

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## COMMENTARY

This is a very timely consideration of the use of drugs that are necessary for an athlete's health, but which in other settings increase physical or mental ability. The requisite timely disclosure of the clinical appropriateness of a given treatment is discussed and is a foundation for sport medicine to build upon.

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