**Title - Is it ethical to administer drugs to a normal individual in a nonpathological situation?**

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**Abstract**

The IAAF regulations on eligibility criteria to compete as female in female competitions in middle distance track events has barred individuals with DSDs wherein the circulating testosterone levels are more than 5nmol/L. They can compete in female category provided they take anti-testosterone treatment and also comply with the restricted testosterone levels. Caster Semenya case is in news again along with whether these IAAF regulations released are fair, scientific, discriminative. Medical Associations are opposed to administer anti- testosterone drugs in non-pathological conditions. This article debates this ethical issue threadbare from all dimensions.

**Is it ethical to administer drugs to a normal individual in a nonpathological situation?**

Caster Semenya case is again in news1 but this time even medical community is entangled with the debate. The status of her having DSD (Differences of Sex Development) is the bone of contention. The CAS (Court of Arbitration for Sports) upholding the IAAF (International Association of Athletics Federation) regulation1, 2,3 to ask individuals with higher testosterone levels, if they want to compete as females, then they should have testosterone levels below 5 nmol/L; if not then should take treatment to lower the levels of testosterone. This brings us to debate of several issues.

**Is it ethical for a medical practitioner to administer anti-testosterone drugs to a normal individual in a nonpathological situation?**

All medical practitioners across the globe are required to act to the benefit of the patient they care, if not atleast cause no harm to the patient while they care. But now with the IAAF regulation if they are administering anti-testosterone drugs1,2,3 to a normal individual (sportsperson) in a nonpathological condition, are they not violating the ethical principles of Beneficence and Nonmalfeasence. Can any medical practitioner forcibly treat the individual (sportsperson) violating their Autonomy? Obviously not without the informed consent of the sportsperson. Are doctors working in Sports academies (Government run?) have duty to care towards the Sports academy /Government or the individual sportsperson. Are sportspersons having such liberty to choose once they have hit the fame or celebrity status? Can Societies / Government / Regulatory bodies force such treatment on sportspersons because sportspersons are representing the nation and thus, they are national property or they are doing their duty to Sovereign / Country? Medical practitioners according to Code of ethics4 have a duty to treat the sick and injured and not everyone. Here the sportsperson is neither sick because of DSD (Differences of Sex Development) nor is injured to be treated with anti-testosterone drugs. If some body argues medical practitioner as clinician5 to provide healthcare which includes promotive care apart from Curative care, Preventive care, Palliative care & Holistic care; the counter argument would be that administering anti-testosterone drugs cannot become Promotive healthcare, that too against the interests and consent of the person being treated! And also modifying the healthy body to produce some ill effects (short term and long term) cannot be termed Promotive healthcare as World Health Organisation defines health promotion as improving quality of life6.

**Are all individuals with DSD or hyperandrogenism barred from all sports competitions?**

All individuals with DSD or Hyperandrogenism are not barred from all sports competitions. The IAAF has clarified2 only for international competitions the following DSDs - 5α-reductase type 2 deficiency, partial androgen insensitivity syndrome (PAIS), 17β-hydroxysteroid dehydrogenase type 3 (17β- HSD3) deficiency, ovo-testicular DSD, any other genetic disorder involving disordered gonadal steroidogenesis are barred from competing in female category events that too middle distance track events (400m to a mile distance) both individual and relay competitions. In addition, these individuals of DSD to be barred should have circulating blood levels of testosterone above 5nmol/L and should have sufficient androgen sensitivity for those levels of testosterone to have a material androgenising effect. And all hyperandrogenism (polycystic ovarian syndrome, androgen insensitivity syndrome)3 exhibiting females are not barred as their circulating blood levels of testosterone are below 5nmol/L.

**Could Sex reassigned individuals participate in sporting events of their choice?**

All Sex reassigned individuals cannot participate in sporting events of their choice immediately after the surgery. The IAAF has implemented some regulations to follow. Individuals undergoing female to male sex reassignment can participate in all male events provided their sex identifying certificate and legal documents (passport) are proper. But for those individuals undergoing male to female sex reassignment should comply with the IAAF regulations to be eligible to participate in female events after a 12month period and if their circulating blood testosterone levels comply to those specified for female competitions2,7,8.

**Are Statements and official positions held by medical bodies of no value in legal discourse?**

IAAF is the supreme body to regulate athletics in the world and its regulations are binding on to all national athletics federations2. But in Caster Semenya case the World Medical Association has urged physicians across the globe (114 national medical associations) not to follow the IAAF regulations. It reminds physicians that administering anti testosterone drugs in a non-pathological condition is against medical ethics and also artificially modifying blood constituents, biochemistry or endogenous testosterone is harmful to the individual9. Similarly, the South African Medical Association has urged the IAAF to review its stance as the science used by IAAF is flawed10 and calls for better and extensive scientific research on this contentious issue. In response the IAAF has brought all its evidence to public domain and has urged World Medical Association to revise its stand based on available scientific evidence11. Thus, each Associations sticking to their stand the issue is getting more complex but nobody can prevent another from taking a dissenting stand. But what matters in a legal battle is evidence. Currently the IAAF has convinced the CAS by presenting its scientific evidence to get its regulations upheld2. Caster Semenya has also right to appeal to Switzerland Federal Courts within 30 days challenging the IAAF stand but with evidence.

**Can you test for testosterone levels without informed consent?**

Though IAAF clarifies that informed consent has to be obtained at all levels even for all the three levels of examination and testing2, and the athlete has to volunteer for blood and urine samples for testing testosterone levels by gas chromatography / liquid chromatography and mass spectrometry, there are enough rumours that in Caster Semenya case in 2009 the Athletics South Africa1 had secretly tested for gender. It would violate ethical principles to forcibly test for any medical finding in any individual unless a law permits it in cases of certain crimes in certain countries12. Even Sex verification tests have undergone sufficient modifications with evolving times13.

**Do higher testosterone levels give unfair advantage in sports events for females?**

Whenever there are higher levels of circulating testosterone levels in a female with properly functioning androgen receptors then there is definite increase in muscle mass and muscle strength, circulating haemoglobin levels and thus the sporting potential3. Thus, IAAF has restricted to compete in female competitions an individual should have less than 5nmol/L circulating testosterone levels to remove any unfair advantage to any female competing in 400m to a mile middle distance track event14. It also specifies a six-month window period even after administering anti-testosterone treatment to remove any residual effect of previous raised testosterone levels 2,3.

**Can policies (with far reaching effects) be made on findings of single research study?**

It would be unfair to make policies (with far reaching effects relying on single research study. In Caster Semenya case the World Medical Association9 has lamented on IAAF on relying on a single research study and South African Medical Association10 has criticised IAAF on relying on flawed research evidence. But IAAF insists it has relied on fifteen years of scientific research evidence and thus it could convince CAS to upheld its regulations11.

**Should journals retract published studies when they find it to be faulty in design, analysis, conclusions drawn, extrapolated results / effects?**

Research should be done with scientific rigour, evidence-based practice and following medical ethics. Everyday there is new scientific evidence being detected and good journals always retract their publications immediately after new scientific evidence is found contrary to what was earlier published15. In IAAF regulations it specifies it would relook and take fresh stand on availability of new scientific evidence2 on the cases of DSDs.

**Are researchers being gender insensitive or discriminative?**

The allegation by Caster Semenya is that IAAF’s stand is biased and discriminatory and the regulations are framed just keeping her in mind and to disqualify her and the entire research evidence presented by IAAF is discriminative2. Is IAAF being gender insensitive or discriminative. But the Regulations clarify to maintain privacy, confidentiality and seeking informed consent, choice of athletics ombudsman2 for the athlete and also claim its research evidence is based on fifteen years of multiple research studies published in standard journals. There are now journals insisting the researchers to comply with gender norms in their research16, 17. There are enough gender toolkits for researchers to comply with gender norms to avoid being gender insensitive or gender discriminatory18.

**If administering banned drugs to enhance performance in sports is doping then what should we call administering drugs to decrease performance in sports? That too when administering such drugs is forced on athletes, with their autonomy compromised, and are forced for treatment being caught between to choose career at one end and ensuring their rights are not violated.**

If administering banned drugs to enhance performance in sports is doping then what should we call administering drugs to decrease performance in sports? Is it fair? That too when administering such drugs is forced on athletes, with their autonomy compromised, and are forced for treatment being caught between to choose career at one end and ensuring their rights are not violated. Should we administer anti testosterone drugs in a non-pathological condition. Are the effects of naturally available testosterone along with long term effects of malignancy to be thought of in forcing / convincing the DSD individual to consume anti- testosterone drugs. How do we justify the harmful effects of infertility, mood changes, cardiovascular diseases of anti-testosterone drugs?

**Is too much of Science interfering in sports?**

Yes, today there is lot of Science involved in Sports. Whether it is training, performance, preventing injuries, recovering from injuries. The IAAF has a separate Health and Science division in advising on all aspects of training, performance, prevention of injuries, advocacy on promotion of health. Doping has brought in much science to detect, prevent this menace from giving undue/illegal advantage to dopers. Other area is of DSDs and sex identification and another of age estimation. But proper scientific evidence which is peer reviewed, acceptable and evidence based is the need of the hour to convince all stakeholders.

**Are not today’s sports played with sportsmanship? Should we not play sports with Fairness?**

Sportsmanship is an important attribute of sports. But several imposters whether on sex identity, age estimated or on performance enhancing drugs or chemicals have brought the debate on whether the deserving person won the sport. The IAAF argument of bringing these regulations2 to bring fairness to female competitions by barring those cases of DSDs who had undue advantage due to their circulating blood testosterone levels have to be judged with caution. Because there are several genetic issues which give advantages to several sportspersons due to their increased height (Basketball), more arm span (swimming), more lung capacity (athletics, etc) but the Sports bodies / regulators are silent on them. So, would it be fair to restrict one genetic abnormality and allow another genetic abnormality in Sports.

**What is the status of Sports Medicine Globally and in India? Is quality research happening in** **Sports Medicine?**

Sports Medicine is an upcoming field in Medical Science. There are a few specialists in developed countries but Indian scenario is not encouraging. As there are only few takers for sports medicine thus the research in this arena is also poor / limited. So, the policy makers have to rely on whatever is the available research evidence / published medical literature. So even in DSDs also we are caught with limited available quality research which is peer reviewed, acceptable, based on evidence-based practice, complying to medical ethics and legal standards.

**Conclusion**

The IAAF regulations in case of certain individuals with DSDs to compete in female competitions in certain track events, has opened a debate should a doctor participate in complying to the regulation requirements for an athlete in nonpathological conditions. Medical principles of Beneficence, Nonmalfeasence and Autonomy are compromised. It also challenges on widely accepted evidence based medical practice. Medical Associations have issued policy statements. The doctors are now to exercise their actions balancing ethics, legal requirement and scientific evidence.

**Conflict of interest** – I hereby declare I have no conflict of interest in this issue/topic nor any association involved with this issue/topic.

**References**

1. In the Ruling against Caster Semenya, bogus science is being used to stifle the vulnerable, available online at <https://thewire.in/the-sciences/caster-semenya-ruling-bogus-science-stifle-vulnerable>, accessed on 2/6/2019
2. IAAF eligibility regulations for female classification (Athletes with differences of sex development) available online at [file:///C:/Users/foren/Downloads/IAAF%20Eligibility%20Regulations%20for%20the%20Female%20Classi.pdf](file:///C:\Users\foren\Downloads\IAAF%20Eligibility%20Regulations%20for%20the%20Female%20Classi.pdf), accessed on 2/6/2019
3. Eligibility regulations for female classification (Athletes with differences of sex development) Explanatory notes/ Q&A available online at <file:///C:/Users/foren/Downloads/Explanatory%20Notes_%20IAAF%20Eligibility%20Regulations%20fo.pdf> , accessed on 2/6/2019
4. Code of Medical Ethics, 2002 available online at <https://old.mciindia.org/RulesandRegulations/CodeofMedicalEthicsRegulations2002.aspx>, accessed on 2/6/2019
5. Competency based Undergraduate curriculum for the Indian medical graduate, available online at <https://www.mciindia.org/CMS/wp-content/uploads/2019/01/UG-Curriculum-Vol-II.pdf>, accessed on 2/6/2019
6. What is health promotion, available online at <https://www.who.int/features/qa/health-promotion/en/>, accessed on 2/6/2019
7. IAAF Regulations governing eligibility of athletes who have undergone sex reassignment to compete in women’s competition, available online at [file:///C:/Users/foren/Downloads/IAAF%20Regulations%20Governing%20Eligibility%20of%20Athletes.pdf](file:///C:\Users\foren\Downloads\IAAF%20Regulations%20Governing%20Eligibility%20of%20Athletes.pdf) , accessed on 2/6/2019
8. IOC Consensus meeting on sex reassignment and hyperandrogenism, November 2015, available online at <https://stillmed.olympic.org/Documents/Commissions_PDFfiles/Medical_commission/2015-11_ioc_consensus_meeting_on_sex_reassignment_and_hyperandrogenism-en.pdf>, accessed on 2/6/2019
9. WMA urges physicians not to implement IAAF rules on classifying women athletes, available online at <https://www.wma.net/news-post/wma-urges-physicians-not-to-implement-iaaf-rules-on-classifying-women-athletes/>, accessed on 2/6/2019
10. SA Medical association says science used by IAAF in Caster Semenya case is flawed, available online at <https://www.iol.co.za/sport/athletics/sa-medical-association-says-science-used-by-iaaf-in-caster-semenya-case-is-flawed-19563844>, accessed on 2/6/2019
11. IAAF hits back at World Medical Association as Caster Semenya row continues, available online at <https://www.irishexaminer.com/breakingnews/sport/iaaf-hits-back-at-world-medical-association-as-caster-semenya-row-continues-922797.html>, accessed on 2/6/2019
12. Singapore Criminal Law (Temporary Provisions) Act, section 27A, available online at <https://sso.agc.gov.sg/Act/CLTPA1955?ProvIds=P1IV-.>, accessed on 2/6/2019
13. Jagadeesh N, Sex verification tests, ethical, legal and social aspects, available online at <https://ijme.in/articles/sex-verification-tests-ethical-legal-and-social-aspects/?galley=html>, accessed on 2/6/2019
14. Bermon and Garnier  (2017), Serum androgen levels and  their  relation  to performance in  track  and  field:    mass  spectrometry  results  from  2127  observations  in  male  and  female  elite  athletes,  Br  J  Sports Med 2017;0:1‐7, available online at <https://www.researchgate.net/publication/318195723_Serum_androgen_levels_and_their_relation_to_performance_in_track_and_field_Mass_spectrometry_results_from_2127_observations_in_male_and_female_elite_athletes>, accessed on 2/6/2019
15. BMJ retracts data on statin side effects, available online at <https://www.pharmaceutical-journal.com/news-and-analysis/bmj-retracts-data-on-statin-side-effects/11138412.article?firstPass=false>, accessed on 2/6/2019
16. Integrating Gender perspectives in the work of WHO, available online at <https://www.who.int/gender/mainstreaming/ENGwhole.pdf>, accessed on 2/6/2019
17. Sex and Gender reporting in global health: new editorial policies, available online at <https://gh.bmj.com/content/3/4/e001038>, accessed on 2/6/2019
18. Toolkit for integrating Gender sensitive approach into research and teaching, available online at <https://eige.europa.eu/sites/default/files/garcia_toolkit_gender_research_teaching.pdf>, accessed on 2/6/2019