**Title - Isssues to consider before administering drugs to a normal individual in a nonpathological situation**

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**Abstract**

The International Association of Athletics Federation (IAAF) regulations on eligibility criteria to compete as female in female competitions in middle distance track events has barred individuals with differences of Sex development (DSD) 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, the South African athlete who was asked by IAAF in 2009 to undergo sex verification tests to prove herself as female, and was prevented from competing in world athletics events till the same IAAF in 2010 cleared her name eligible to compete in world athletics events. 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 all the issues threadbare from all dimensions.

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

Caster Semenya, the South African athlete who was asked by IAAF in 2009 to undergo sex verification tests to prove herself as female, and was prevented from competing in world athletics events till the same IAAF in 2010 cleared her name eligible to compete in world athletics events. 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, just because sportspersons are representing the nation and thus, they are national property/ assets or they are doing their duty to Sovereign / Country? In reality sports persons are forced to undergo treatment as they have been left with no choice except to take treatment for lowering testosterone levels – as there would be enough pressures from sports team members, trainers, coaches, administrators, ministry and Governments for the sake of the fame, country, medals, recognition, etc.

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 by consuming anti-testosterone drugs (short term and long term) cannot be termed Promotive healthcare as World Health Organisation defines health promotion as improving quality of life6. The harmful effects of consumption of anti-testosterone drugs are hot flashes, feeling of tiredness, anaemia, loss of skeletal muscle mass, sexual dysfunctions, infertility, bone loss, bone fractures, cardiovascular diseases, memory loss, mood changes including emotional instability, depression, etc. cannot be termed as Promotive healthcare as it affects health of the person.

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

As per IAAF guidelines 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.This argument of IAAF barring individuals with circulating blood levels of testosterone above 5nmol/L could be because of the IAAF evidence of increased muscle bulk and increased muscle power as a result of such testosterone levels. And if such individuals are allowed to compete in female events it would be unjust and unfair to compete as remaining competing females may not have the same advantages of increased blood testosterone levels in their blood circulation2. But the counterarguments are - if once all individuals are categorised or grouped as one (female) then there should not be any discrimination amongst those individuals of the group based on characteristics which are not induced (intentional or accidental) and also which are congenital (born with) or genetic (hereditary) or for which the individual had no control. Another counterargument is of World Medical Association claiming such testosterone levels in individuals with DSDs are due to genetic variation of female athletes and any attempt to reduce those testosterone levels just because to make them eligible to compete in a female sports event (which is not pathological) would amount to violation of international medical ethics and also human rights standards. 9 In addition such efforts to reduce testosterone levels are harmful to the individual. Another counter argument of South African medical Association is that IAAF asking individuals with DSDs to reduce their testosterone levels before becoming eligible to participate in female sporting events is based on a single flawed research and not based on scientific rigour, medical ethics or evidence based practice10. Another counterargument is that we are not able to definitely distinguish the urinary metabolites of exogenous origin testosterone to endogenous origin testosterone and thus there are possibilities of false positive results. Hence asking / blaming someone to reduce their testosterone levels for which they had no control, and when current science could not exactly pinpoint their (individuals with DSDs) fault would be against the principles of natural justice. 11

**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 evidence12. IAAF is claiming its stand is based on 15 years of scientific publications and observations from the field; even the Court for Arbitration in Sports has accepted the validity of evidence presented by IAAF. 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 had right to appeal to Switzerland Federal Courts within 30 days challenging the IAAF stand but with evidence. And on appeal the Switzerland Federal Courts have suspended the IAAF regulations on testosterone levels with immediate effect giving relief to Caster Semenya13.

**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 countries14. Even Sex verification tests have undergone sufficient modifications with evolving times15. Hence proper informed consent with explanations to diurnal variations in testosterone levels, levels altering with training/exercise / competitions have to be explained. Even the difficulties in distinguishing metabolites of exogenous and endogenous testosterone have to be discussed11.

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

Testosterone levels would improve the anabolic effects, muscle building abilities, improve confidence levels11.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 event16. 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 regulations12.

**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 research, 17,18. There are enough gender toolkits for researchers to comply with gender norms to avoid being gender insensitive or gender discriminatory19.

**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 before forcing in / convincing the DSD individual to consume anti- testosterone drugs. How do we justify the harmful effects of anti-testosterone drugs like infertility, mood changes, cardiovascular diseases?

**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. Even players practising fasting (for example Roza by muslim players in holy month of Ramazan) are also given advice on diet type and quantity to be consumed, fluid management, fitness and exercises based on Science.

Doping has brought in much science to detect, prevent this menace from giving undue/illegal advantage to dopers. We have scientific ways to detect the usage of banned drugs and substances from various body fluids. Other areas are of Age estimation / DSDs and sex identification – which are based on various scientific issues/evidence. 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. It is a fair, polite, ethical and appropriate behaviour while playing sports exhibited by sportspersons. But several imposters (who do not demonstrate sportsmanship) 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. It’s a multidisciplinary field covering curative, rehabilitative and preventive aspects of competitive and recreational athletes. The purpose of Sports Medicine is to maintain sportspersons, health, fitness, strength and prevent / treat injuries by continuous research. It helps in consistent performance by players by increasing their maximum capabilities without consuming any drugs or banned substances. There are a few such specialists in developed countries guiding their players to achieve glory 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. Sports Medicine specialists should conduct research at multiple sites/countries with large samples on the issue whether individuals with DSDs playing sports in general and athletics in particular have any undue advantage because of their genetic abnormality. Unfortunately, in India such specialists being less are overburdened with curative / rehabilitative roles rather than involving in research.

**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.

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