

# Prohibited substance regulation and compliance testing: A principalism approach

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**Background.** Prohibited substance regulation and compliance-testing programmes are required to minimise risks to health and safety in the workplace due to inappropriate use of legal (alcohol, cannabis) and illegal substances. A compliance drug test is, in principle, an invasive biomedical intervention that infringes on the autonomy and other rights of the individual, giving rise to ethical dilemmas.

**Objectives.** To employ Beauchamp and Childress' principalism approach to reason and to motivate for the minimum ethical requirements for this type of biomedical intervention.

**Methods.** The ethical aspects relevant to the mandatory guidelines of the Substance Abuse and Mental Health Services Administration of the USA (SAMHSA) protocols and procedures were extracted and interpreted with reference to the principalism approach.

**Results.** The principalism approach was found to be highly applicable to the ethical requirements of a prohibited substance regulation and testing programme.

**Conclusion.** Ethical dilemmas could be explained and motivated by using the four principles of respect for autonomy, beneficence, non-maleficence and justice as a starting point.

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Prohibited substance regulation and compliance testing have become prominent in the South African (SA) context since the Constitutional Court legalised the possession of cannabis for personal use by adults.<sup>[1]</sup> Administrators, as well as users of legal and illegal drugs, are now highly sensitised to the issue, and much focus is drawn to the legal, ethical and scientific aspects of drug use to ensure that an organisation's drug testing policies are legally defensible.

The compounds that are regulated in a compliance-testing environment typically include legal substances such as alcohol and cannabis, as well as illegal substances such as cocaine, amphetamines and heroin. These compounds have the ability to impair an individual's faculties negatively with regard to functioning in risk- and safety-sensitive environments. Some prescription and over-the-counter medications also have impairment potential, and are therefore also listed as part of a formal policy or guideline. The numerous claims that cannabis has medicinal properties have intensified the debate, since individuals feel they have the right to self-medicate, especially with a legal drug.

Although a prohibited substance test has the intent of monitoring compliance rather than a medical diagnostic aim, it is essential to recognise that it is still a biomedical intervention on a human, which requires an ethical and legal approach similar to that applied by the medical profession in relation to human rights. The general sensitivity and urge within the medical law and ethics environment to respect human rights such as privacy, dignity and bodily integrity led to the realisation that a similar approach must be followed when proposing a regulatory framework for prohibited substance regulation and testing programmes. Prohibited substance testing in a human, by its

very nature, is invasive, and constitutes infringements on the rights to freedom, autonomy and privacy, which results in ethical dilemmas that need to be addressed in a sound fashion.

Prohibited substance regulation and testing programmes in SA are in most instances overseen by individuals who do not have the necessary legal, ethical or scientific backgrounds, which may result in the infringement of the human rights of the individuals or test subjects.

The present study proposes the use of the principalism approach, as described by Beauchamp and Childress,<sup>[2]</sup> as an ethical framework to address ethical dilemmas that arise in a prohibited substance regulation programme. The principalism approach is a pronounced applied ethical theory, claiming that individuals have a common morality based mainly on four norms, also called principles.

## Methods

SA does not have mandatory guidelines similar to those in the USA, which are administrated by the Substance Abuse and Mental Health Services Administration (SAMHSA).<sup>[3]</sup> The individual steps in the mandatory testing guidelines were identified, and the minimum ethical requirements as well as possible ethical dilemmas are highlighted and discussed with reference to the principalism approach. Valuable information was found in the works of Beauchamp and Childress<sup>[2]</sup> on the principalism approach, and also in the work of Emmanuel *et al.*<sup>[4]</sup> regarding ethical clinical research as applied to prohibited substance regulation and testing. The ethical essence of the SA Constitution,<sup>[5]</sup> the National Health Act No. 61 of 2003,<sup>[6]</sup> the Health Professions Act No. 56 of 1974<sup>[7]</sup> and professional guidelines

for the medical profession includes a vast amount of ethical principles that can be sourced from.

## Results

### Mandatory guidelines by SAMHSA

The main aspects and sequence of events in a prohibited substance test, according to the SAMSHA mandatory guidelines, are illustrated in Fig. 1.<sup>[8]</sup> The ethical aspects comprise procedural ethics and professional ethics. The organisation's policy should address the former; the second relates to the individuals acting on behalf of the organisation in terms of their professionalism, which includes qualifications and ethical compliance. There is currently no formal regulatory body for prohibited substance regulation and compliance testing.

A documented policy is the initiating instrument describing the responsibilities of the role players and rules of the programme, ranging from the selection of an individual up to the final decisive action if the test subject is found not to comply with the rules of the programme. A 'zero-tolerance' stance is applicable in the interest of the minimisation of risk.

At first, an individual is selected for preliminary testing in a controlled fashion.

The bodily fluid specimen is donated in a legally defensible fashion, under the supervision of a collection officer who has to ensure the integrity of the specimen. The collection officer performs the preliminary test after securing a portion of the specimen for possible confirmation analysis. If the preliminary test is non-negative, the sampling officer arranges for shipping of the specimen to a forensic laboratory for confirmatory analysis. The test result is then communicated to the medical review officer (MRO) for validation by interviewing the test subject to assess possible culpability in the form of wilful or negligent use. If the latter prevails, the test result is communicated to the designated employer representative (DER), who informs management on the outcome of the test for decisive action.

If the test is for alcohol, a non-negative preliminary screening test result serves the purpose of referring the test subject to an onsite breath-alcohol testing facility for an evidentiary or confirmatory breath alcohol test under the guidance of a breath alcohol technician.

### Principlism approach

The complete process, as well as each of the individual seven steps in the sequence of events, has to be ethically sound. Both the organisation (and its programme

representatives) as well as the individuals who are subjects to the programme have moral obligations that must be respected to ensure a risk-free environment. The principlism approach, as described by Beauchamp and Childress,<sup>[9]</sup> is a pronounced applied ethical approach, suggesting a common morality based mainly on four norms, also called principles. The principles of respect for autonomy, non-maleficence, beneficence and justice find application in terms of common morality as well as professional morality.

Balancing the four norms usually has some constraints when making an ethical decision. Beauchamp proposed six conditions to arise at a reasonable conclusion in the case of ethical dilemmas.<sup>[9]</sup> These are: (i) there must be sufficient reason to act on a norm, which is viewed to have higher priority in the specific case; (ii) the objective of the norm to be followed must have a good chance of achievement; (iii) there are no other morally acceptable alternatives available; (iv) the lowest level of infringement, in line with the goal of the infringement, has been selected; (v) the minimisation of harm principle has been applied to all parties; and (vi) all parties involved have been treated impartially.

### Discussion

#### Respect for autonomy

'A norm of respecting an individual's autonomous decisions.'

Respecting the individual's entitlement to self-rule or self-governance, if (s)he is free from controlling interference and limitations that will inhibit a rational choice, implies that consent must be informed.<sup>[10]</sup> Autonomy should be exercised wilfully, intentionally, with understanding, without controlling influences and with the necessary capacity (or competence) to exercise a decision.

#### Voluntariness in deciding

Voluntary consent involves that a competent individual is not forced or coerced into consent by another person or condition.<sup>[2]</sup> A typical example of where voluntariness is diminished is when an employee is threatened to submit for a drug test or otherwise be 'fired'.

The unsymmetrical employer-employee relationship may inhibit voluntariness when

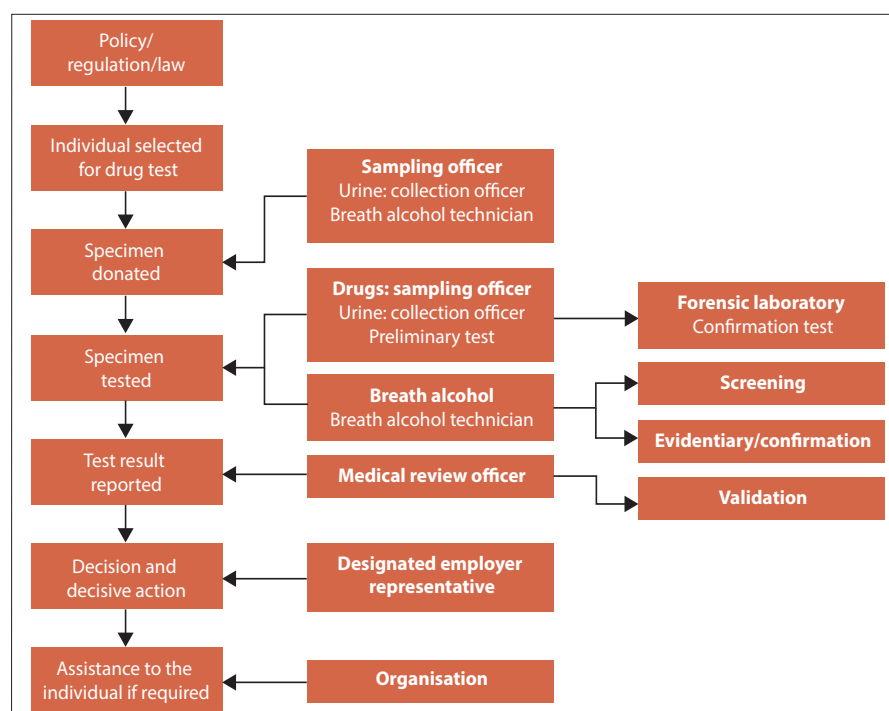


Fig. 1. Sequence of events in a prohibited substance test according to the Substance Abuse and Mental Health Services Administration mandatory guidelines.<sup>[8]</sup>

submitting for a drug test; however, the voluntary element is embedded in the voluntary association of the employee with the specific organisation. An individual should typically be informed of a prohibited substance compliance test at the following stages: (i) when initially joining the organisation; (ii) at the acceptance of the prohibited substance regulation and compliance testing policy; and (iii) immediately before every drug test.

An individual may change his or her mind at any stage during the regulation process or drug test, even if it is in conflict with a previous choice, or contradicts the organisation's policy that the individual has agreed to previously. There may be consequences for him or her, but a refusal to give consent is not an acknowledgement of guilt. Consent is a 'continuous' process, and it may be withdrawn at any stage.<sup>[4]</sup>

### Informed consent

The following opportunities must be part of the information-sharing process before a compliance test: (i) training that an individual receives from the organisation regarding the programme; (ii) the language in which the policy is drafted, which is of importance in the clear understanding of the policy; (iii) information communicated immediately before every compliance test.

The information on a prohibited substance test must be specific. Typical information to be provided is: (i) that the test is a compliance test that may result in punitive action, as opposed to a diagnostic test; (ii) that the test involves a screening test as well as a confirmation test in case of a non-negative screening test result; (iii) what substances will be tested for; (iv) to whom the test results will be disclosed, and in what manner; (v) that the individual may designate a person to receive the result; (vi) that the individual may refuse or withdraw from the test procedure at any stage; and (vii) which forensic laboratory will perform the confirmation test.

The testing officer may also not alter the list of compounds for which consent was provided without the explicit consent of the individual after the specimen was collected. The signing of an informed consent form by a test subject without reading it, merely because (s)he trusts the specimen collection officer, or due to a lack of time, is therefore in principle not informed consent due to a lack of information.

### Capacity

Assessment of competency before a biomedical intervention should be 'focused on whether the individual is cognitively, psychologically and legally capable of adequate decision-making.'<sup>[11]</sup> Someone is regarded as competent if (s)he understands a biomedical intervention, appreciates the risks and benefits and can make a decision in view of this understanding. Seeking consent from an individual in a compliance drug test, such as for workplace, sports doping or school testing, requires an approach that has an element of active enhancement of capacity to decide in combination with information on the consequences that may result from a drug test.

Confidentiality of the screening and confirmation test results must be preserved, and results must be communicated on a need-to-know basis only. The reporting chain typically involves that the confirmation test results are reported by the forensic laboratory to the MRO, who reports only validated positive test results to the DER, who in turn will give the information to the human resources departments. The MRO must inform the test subject before the validated positive test result is communicated to the DER.

### Beneficence

'A group of norms related to relieving, minimising or preventing harm, and providing benefits and balancing benefits against risks and costs (limited).'

Promoting health, safety and other essential interests of colleagues and the organisational goals complies with the principle of beneficence. The minimisation of risk must be the primary driver of a prohibited substance regulation and testing programme. Beneficence should, however, be balanced against non-maleficence by not causing harm to an individual, with protocols that result in unreliable test results and unfair treatment of a test subject.

Acts that can promote beneficence in the drug regulatory environment are: (i) responsible and rational listing of prohibited substances and their corresponding threshold levels, as opposed to indiscriminate enlisting of all suspect substances; (ii) drafting of a policy in such a manner that it protects the interests of all and promotes the health and safety of all; (iii) compliance of subjects as well as testing officials with the policy; (iv) ensuring accurate drug testing results by using a competent and accredited confirmation testing facility; and (v) providing assistance to a drug addict or alcoholic.

### Non-maleficence

'A norm of avoiding harm' (unlimited).

Non-maleficence is a norm of avoiding harm in an unlimited fashion, and has to do with the intentional avoidance of actions that may inflict harm or evil.<sup>[12]</sup>

The following can all be viewed as ways of inflicting harm or evil during the drug regulatory process: dishonesty; wilful or negligent use of prohibited substances; inaccurate and unreliable test results; the use of non-validated and inaccurate testing devices and protocols; an incorrect or unfair policy; disclosing test results without consent; enlisting a compound with medicinal benefits if it does not have impairment properties; being intoxicated in safety- or risk-sensitive environments; disclosure of personal information without consent; and professional negligence.

### Negligence and the standard of care

In addition to not inflicting harm, non-maleficence includes obligations not to impose risks that may lead to harm, such as the non-disclosure of an individual's drug-taking habits by a doctor to the employer when others in the workplace may be in danger, or to the parents in the case of a child whose life may be endangered.

Ignorance regarding the standard of due care is viewed as negligence, which can be either intentional (attentively or knowingly) or unintentional (inattentively). An example of the first is to disclose a drug test result to the employer without the individual's consent, or to force an individual into donating a specimen without his or her consent, or for a forensic scientist to report an incorrect result knowingly or negligently. An organisation in an environment where serious harm can be inflicted due to the working conditions without a prohibited substance policy or ignoring the policy also falls in this category.

Examples of the second category of unintentionally or inattentively causing harm are: (i) a forensic scientist does not take due care to

prevent the reporting of incorrect test results; or (ii) adequately validated methods according to professional standards and scientific principles are not used; or (iii) a collection officer does not take due care to prevent contamination of the specimen during the collection process.

## Justice

'A group of norms for fair distribution of benefits, risks, and costs.'

Justice refers to the principle of fairness, and in prohibited substance regulation, more specifically, to the fair treatment of the individuals subjected to the policy of the organisation. The principle of justice in a prohibited substance regulation programme refers to: (i) legal justice; (ii) rights-based justice; (iii) distributive justice; (iv) procedural justice; and (v) social justice.

Legal justice relates to respecting morally sound laws, and is an essential ethical requirement in complying with the principle of justice. Rights-based justice is provided for in chapter 2 of the Bill of Rights of the Constitution of SA.<sup>[5]</sup> Rights also have a reciprocal relationship with obligations, in the sense that the compliance of an organisation with the specific right of an individual creates an obligation for the individual to respect the effort of the organisation. For example, if an organisation has a policy that respects autonomy and that prohibits the use of dangerous mind-altering drugs for the sake of safety or to minimise harm, the individual should respect the policy of the organisation by avoiding the consumption of such compounds in a manner that is forbidden by the policy. Distributive justice has to do with how fairly the outcomes of a prohibited substance regulation policy are distributed. A question that may be asked to assess distributive justice in a prohibited substance regulation programme is: 'Is everybody treated equally and without unfair discrimination?'<sup>[13-15]</sup>

Procedural justice focuses on the fairness of the outcome of a procedure or intervention.<sup>[16,17]</sup> Fair procedural justice in a prohibited substance regulatory intervention requires the process itself to be fair. A prohibited substance policy should be examined from both a distributive and procedural justice perspective.<sup>[18-22]</sup> Leventhal<sup>[23]</sup> claimed that a policy has to comply with the following four principles of distributive justice, namely, consistency, ethicality, accuracy and correctability. These are all related to the fairness and 'distribution of the outcome'.

A prohibited substance testing programme is consistent if it applies to all members of the organisation equitably, which means that the policy should not be applied for specific groups or individuals in the organisation only, for instance when management is not tested but everybody else is. Ethicality in this instance refers to the notion that the punishment must be in proportion to the violation. Accuracy refers to the reliability with which the procedure can detect prohibited substance use. False-positive detections must be at a minimum to be confirmed accurate. Correctability refers to the inclusion of rehabilitation or an assistance programme to correct the individual's behaviour, as well as whether the violation will be 'forgotten or forgiven' and deleted from his or her record.

Social justice relates to perceptions of fairness, and should be viewed in terms of the social context within which prohibited substance testing is performed. Situational variables such as

interpersonal treatment, organisational reputation and testing context also affect the perception of procedural fairness. Human beings require treatment that confirms dignity and respect before, during and after a prohibited substance test. The 'voice effect' is also a long-standing issue in the perception of fairness.<sup>[24]</sup> A proven record of providing fair treatment to individuals by the organisation also contributes to a positive perception of fair treatment.<sup>[25]</sup>

## Conclusion

The principlism approach was found to be a suitable ethical framework to solve ethical dilemmas that arise in a biomedical intervention such as a prohibited substances regulation and compliance-testing programme. The four principals of respect for autonomy, beneficence, non-maleficence and justice find application in each of the steps of a programme that complies with due procedure.

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