

Should Informed Consent Be Required for Laboratory Testing for Drugs of Abuse in Medical Settings?

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Laboratory testing for drugs of abuse is often conducted in medical settings, with little consideration of the technical limitations and the potential for legal and social harm to the patient. We consider several technical problems associated with such testing, including the lack of chain-of-custody procedures, the possibility of false-positive results with screening immunoassays, and the infrequency of confirmatory testing. Important ethical issues arise because of the sensitive nature of drug test results,

the ramifications of false-positive results, the limitations of confidentiality protection, and the practice of testing without the patient's knowledge. Taken together, these technical and ethical concerns suggest that drug testing policies in medical settings should specify which conditions require explicit informed consent, as well as create procedures for protecting this sensitive information. *Am J Med.* 2003;115:54–58. ©2003 by Excerpta Medica Inc.

The clinical diagnosis of substance abuse is generally based on the medical and psychosocial history rather than laboratory testing. However, a clinician can choose to order laboratory tests for detecting drugs of abuse when evaluating a patient with known or suspected substance abuse (1). Because of the limitations of current screening assays, the clinician needs to know which tests to order and, importantly, the sensitivity and specificity of a given test. In addition, the clinician should consider privacy and confidentiality issues. In this article, we review the issues associated with substance abuse testing in medical settings and outline an approach for informed consent that safeguards the privacy and autonomy rights of patients.

Why Test for Substance Abuse?

Laboratory tests are usually ordered to make or exclude a diagnosis, screen for disease, or guide treatment plans. In the case of substance abuse, most testing occurs in the emergency setting. Given that substance abuse is often associated with major trauma (2), the American Medical Association (3) recommends alcohol and drug screening in hospitalized trauma victims. Drug testing is also rec-

ommended in young patients who present with myocardial infarction, especially if they have no other risk factors for coronary disease, because cocaine use has been associated with chest pain (4). In patients presenting with drug overdose, urine screenings may help to identify the drugs involved and to guide specific treatment (5).

The frequency and utility of laboratory testing for substance abuse in nonemergent clinical settings is not known. However, some situations warrant clinical suspicion; for example, substance abuse associated with an illness, such as diabetic ketoacidosis (6). Certain complications of pregnancy, such as placental abruption and intrauterine growth retardation, can also be associated with substance abuse. In addition, identifying drug use among pregnant women is important in ensuring the health of newborns.

How Does a Positive Drug Screen Affect Treatment?

Acute overdoses can require immediate specific treatment, such as naloxone for heroin overdoses. However, treatment for most overdoses is supportive and given before the results of drug testing are available. Indeed, many emergency medical system and emergency department protocols use a "cocktail" approach in obtunded patients, in which naloxone and other substances are administered empirically. In one study, the results of qualitative drug screens affected immediate management in less than 5% of emergency department patients with suspected drug overdoses (7). Another study found that urine drug testing had no effect on the immediate management of trauma patients (8). By contrast, identification of cocaine use in patients with ischemic chest pain is important and

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may lead to changes in management; nitroglycerin and calcium channel blockers, but not beta-blockers, are the preferred drugs in patients with cocaine-induced myocardial ischemia (9).

Although drug screen results can sometimes lead to specific treatments, it is not known if testing improves the treatment of substance abuse through counseling and referral to drug treatment programs. Studies have reported that counseling trauma patients with alcohol problems in the emergency setting reduced re-injury rates (10), but there are no data on outcomes associated with counseling trauma patients who use illicit drugs. In the hospital setting, one study found that among patients with positive urine drug screens for cocaine, 29% had documented counseling and 34% were referred for substance abuse treatment (11), suggesting that physician response to positive drug tests varies.

ISSUES ASSOCIATED WITH TESTING FOR DRUG ABUSE

Limitations of Clinical Laboratory Testing

Currently, the most common testing procedures involve screening immunoassays, which are quick, automated, and inexpensive (12). A urine drug screen usually consists of a panel of immunoassays established by the local laboratory for the five drugs mandated for testing in the federal workplace—amphetamines, cocaine, marijuana, opiates, and phencyclidine—as well as for other commonly abused drugs, such as barbiturates and benzodiazepines. These immunoassays have limitations. For instance, cutoff levels are assigned arbitrarily in most laboratories. Although chosen to minimize false-positive and false-negative results, cutoffs rarely correlate with intoxication, impairment, or dependence. One major limitation is that the antibodies used in the assays can cross-react with other structurally similar substances, thereby producing false-positive results (1,13). Several sympathomimetic amines have cross-reactivity with the amphetamine immunoassays (14). False-positive results can also be seen in persons taking decongestants, appetite suppressants, or drugs for Parkinson's disease. Opiate immunoassays may be difficult to interpret in persons who consume poppy seeds, which contain small amounts of morphine and codeine. Persons who eat baked products containing poppy seeds can excrete small amounts of these opiates, which may be detected with standard clinical urine assays (15). A person who smokes one marijuana cigarette can have a positive test 1 to 2 days later with a screening immunoassay that uses a 50-ng/mL cutoff (16). Heavy smokers can test positive as many as 46 days later using the 20-ng/mL cutoff (17). Thus, the urine drug screen for marijuana may detect prior use that may not be relevant to the current clinical problem.

Comparisons of Federal Workplace Testing and Clinical Testing

Drug testing has become much more sophisticated and regulated in the federal workplace and forensic settings, as compared with in the clinical setting. In the workplace, employees may be subjected to drug testing during or after employment but are informed that the urine specimen is for drug testing. In contrast, patients may not realize that the specimens collected are to be tested for substance abuse.

Federal regulations also mandate specific procedures for the collection and processing of specimens in workplace testing, with chain-of-custody requirements to safeguard the integrity of the handling process (18). There is no such requirement in the clinical setting. Federal regulations also require confirmation of positive screening tests with gas chromatography/mass spectroscopy (19,20). Although there are no published surveys that document the use of gas chromatography/mass spectroscopy for confirmation of screening tests, or chain-of-custody policies for the handling of specimens, our experience in the clinical setting is that neither is readily available or ordered routinely.

Lack of Informed Consent in Clinical Testing

Currently, explicit informed consent is not required for clinical drug testing (21). In many cases, such as trauma or overdose, explicit consent is not possible. However, even when substance abuse is suspected and the patient is able to provide consent, clinicians often order drug testing without the patient's knowledge and consent. Although the motive may be to make a diagnosis or to convince the patient to accept treatment for substance abuse, patients may feel betrayed when they learn that they were tested for substance abuse without their knowledge. This situation could weaken the physician-patient relationship and the patient's willingness to seek care in the future.

Implications of a Positive Test

The diagnosis of illicit substance abuse may have legal and social ramifications. More than 30 states have adopted a provision in their insurance code allowing exclusion of health insurance coverage for injuries related to substance abuse (22). Although the National Association of Insurance Commissioners recently voted to repeal these provisions, there is still great concern about such loss of insurance coverage. Many states require reporting of positive drug screens in pregnant women, with a positive toxicology test in a newborn or mother at delivery considered as evidence of child abuse or neglect (23).

The negative consequences of a positive drug screen can be exacerbated when the patient is unaware that a drug test was ever performed. Furthermore, if there is no second method to confirm the screen, as is often the case, complications could arise from false-positive results.

Privacy and Autonomy

The right to privacy has been articulated in decisions by the U.S. Supreme Court (24). Whenever a person undergoes medical evaluation and treatment, the person's privacy is at risk of being compromised. The most effective means of protecting privacy is by requiring informed consent before testing and treatment (25), which gives the patient the option of preserving privacy by refusing testing, or of risking privacy for the proposed benefits of testing and treatment. The principle of autonomy provides an ethical basis for the right to refuse treatment and the requirement of informed consent. The autonomy principle holds that the patient, rather than the physician, should decide whether to undergo testing or treatment. The physician's obligation is to disclose the benefits and risks of any proposed procedure, to discuss relevant alternatives, and to obtain informed consent (26). If the patient consents to testing, the physician's obligation then becomes one of preserving the confidentiality of the results.

From the perspective of the patient with active substance abuse who does not want treatment, there would be little reason to consent to testing. Unlike with human immunodeficiency virus (HIV) infection, where untested persons are unaware of their antibody status, persons involved with substance abuse know about their own drug use. Testing therefore is not only wasteful, but offers little, if any, benefit to the patient while jeopardizing privacy.

When patients enter into substance abuse treatment programs, consent is obtained for drug testing during the course of treatment to monitor compliance. By contrast, when a patient undergoes standard treatment at a hospital or clinic, only a general consent for testing and treatment is obtained, with no specific mention of testing for drugs of abuse. Most routine testing procedures in hospitalized patients, such as blood and urine testing, do not require a separate formal consent process as they are covered under the general consent to treatment. What is in question is whether drug testing should be considered a routine procedure that is covered by the general consent rule, or whether there is sufficient reason to require explicit formal consent. In a recent U.S. Supreme Court case, which involved testing pregnant women for drugs without their consent and passing on positive results to the local police, the court ruled that such procedures violated patients' rights (27). However, the court declined to clarify whether a general consent to treatment covers current drug testing practices adequately.

Other Tests Requiring Informed Consent: HIV Testing

Testing for HIV generally requires informed consent (28), as does genetic testing for inherited conditions such

as Huntington's disease and the BRCA genes (29), because a positive result in these instances can affect the patient's prognosis, insurance status, and employment. If an insurer or employer becomes aware of these results, a loss of benefits or employment could ensue. The risk of major "informational harm" differentiates HIV and genetic tests from those that fall under the general consent to treatment. Because the results of drug testing can involve a similar risk of informational harms, it is reasonable to require explicit informed consent for drug testing.

Confidentiality

Confidentiality is a foundation of the patient-physician relationship. When patients consent to treatment, there is an implicit understanding that their treatment records will remain private. In the case of substance abuse treatment, the emphasis on confidentiality goes beyond that of general health care. Federal laws require written permission from the patient to disclose information about treatment for alcohol or substance abuse when under the care of federally funded treatment centers, addiction specialists, or specialized alcohol or drug abuse treatment units in general medical facilities (30). These laws were designed to protect the privacy of patients undergoing addiction treatment because the stigma associated with substance abuse and its treatment might discourage patients from seeking help. Although these restrictions do not apply to general medical settings unless patients are there under the care of addiction specialists, state laws may limit disclosure of medical records for patients receiving substance abuse from any provider without the patient's written consent (31). Recently defined Health Insurance Portability and Accountability regulations state that the patient has the right to restrict which information can be released, but they do not have specific provisions for information regarding alcohol and drug abuse (32).

In contrast to concerns about privacy and confidentiality, there is the societal interest in reducing harm to others. In the case of child abuse and certain transmissible diseases, there are mandatory reporting laws. For example, treatment for a patient with tuberculosis can be compelled because the public interest in preventing the spread of the disease outweighs individual autonomy. Although substance abuse directly harms the person engaging in it, there is no social consensus that this situation warrants forced treatment, with one exception being driving under the influence. One could argue that society would benefit from policies that mandate substance abuse testing for all emergency department trauma cases and reporting of positive results to the authorities. However, such policies would need to be enacted through legislation or case law, rather than left to the judgment of

individual physicians. Until then, it would seem most justifiable ethically for physicians and other health care providers to respect patient autonomy and confidentiality in their clinical drug testing practices.

CONCLUSION

Our review suggests that future drug testing policies should require informed consent, with the physician explaining the reason for testing and the intended use of the results. Physicians will need to be familiar with any reporting requirements in their state. In emergency cases involving incapacitated patients, where the results would lead to changes in management, testing could be done under the emergency exemption to informed consent. Testing in adolescents should also require informed consent (33).

In addition, confirmatory testing, if available, should be performed when positive results are disputed by the patient. Results of clinical screening tests should not be considered legal evidence unless testing follows the same guidelines for obtaining legal evidence. Finally, policies should outline procedures for protecting the confidentiality of drug testing information. Such information should be released to insurers and others only when the person tested has given explicit consent, unless there are laws that mandate reporting to authorities.

Implementation of these recommendations would ensure that far less substance abuse laboratory screening would take place in nonemergency medical settings. In many cases, the practice of confronting patients with drug screen results, which has not been shown to be particularly advantageous, would cease, and patient privacy and autonomy would be preserved. Less laboratory testing would not necessarily result in decreased clinical suspicion of substance abuse or reduce physicians' efforts to counsel patients. Physicians could still convey their concerns in a nonjudgmental and nonthreatening manner to any patient suspected of substance abuse (34), discussing these matters in confidence and emphasizing the health risks as well as the benefits of not using such drugs. By requiring informed consent, confirmation on request, and confidentiality, not only is respect for patient autonomy and privacy maintained, but the trust that is essential to the physician-patient relationship is also preserved.

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