

Informed consent for HIV screening in the emergency departments and human rights in patient care: seeking the right balance

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Abstract *HIV exceptionalism refers to the fact that the illness is so different from other diseases that testing needs a special approach to informed consent. HIV infected people often visit health clinics, especially emergency departments, years before receiving a diagnosis without being tested for HIV. There is considerable public interest in increasing HIV testing in emergency departments. However, because these departments are sensitive environments that primarily provide urgent and emergency care, a number of ethical questions have been raised about the appropriateness of these settings for the implementation of universal screening programs. Human rights in patient care therefore constitutes an essential theoretical framework for analyzing ethical and legal dilemmas that arise in clinical encounters, thus strengthening the application of human rights principles to the context of patient care.*

Key words *HIV infections, Screening programs, Human rights, Informed consent, Emergency healthcare*

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Has HIV “exceptionalism” become anachronistic?

HIV exceptionalism refers to the fact that the illness is so different from other diseases that testing needs a special approach to informed consent. HIV testing has therefore involved: (a) exceptional confidentiality protections, as information is so sensitive; (b) exceptional informed consent, because the test is personally invasive; and (c) individualized pre-test counseling, since a positive can be so disruptive¹.

HIV infected people often visit health clinics years before receiving a diagnosis without being tested for HIV². Despite this, it is important to underline that HIV infection falls within the criteria that justify screening: (a) it is a serious health disorder that can be diagnosed early before symptoms develop; (b) it can be detected by reliable, inexpensive, and non-invasive screening tests; (c) patients diagnosed with HIV have years of life to gain if treatment is initiated early, before symptoms develop; and (d) screening programs are cost effective².

With the aim of increasing early detection, tackling stigmatization of HIV testing, combining care and prevention, and ensuring access to immediate treatment, various organizations have encouraged the adoption of screening programs in different clinical settings, including emergency care departments^{2,3}. Screening can help normalize HIV testing and reduce the stigma surrounding the disease, leading to greater test acceptance and increasing the number of people receiving timely diagnosis⁴.

On the other hand, expanding HIV testing and its incorporation into emergency care departments pose a number of ethical challenges for patients, health professionals and health systems, particularly in relation to informed consent. HIV testing in emergency care departments therefore raises issues about human rights applied to clinical settings, such as the right to informed consent, which implies the right to privacy. Thus the theme of HIV testing in emergency care services and limitations of informed consent raise questions about the compatibility between increasing HIV testing in these settings and respect for patient privacy, which encompasses exercising self-determination by means of informed consent. This article explores the ethical aspects of increasing HIV testing in emergency departments, drawing on the framework for human rights in patient care and principlist approach to bioethics and patient rights.

A necessary framework

The concept of “human rights in patient care” (HRPC) refers to the application of human rights principles to the context of patient care⁵ and is used as a tool for analyzing ethical and legal dilemmas that arise in clinical encounters⁶ principlist approach The HRPC approach is underpinned by the understanding that human rights constitute ethical and legal norms capable of guiding reflection and resolving bioethical conflicts, notably in the field of clinical bioethics. HRPC thus provide a theoretical and normative framework for the conduct of professionals, patients, family members and service providers in the context of patient care^{5,7}.

The use of the HRPC framework contributes to a shift in the ethical and legal perspective in patient care, in so far as it is a patient-centered approach in which decisions are guided by the will and preferences of patients without neglecting the rights of care providers. HRPC thus provides a unique frame of reference that widens out from the sphere of the individual, enabling a more systemic and collective approach to addressing problems, thus contributing to the mitigation of the asymmetry of knowledge and power in the traditionally individual and contractual patient-provider relationship. The use of HRPC as a bioethical framework has certain advantages over other principle-based approaches such as *principlism*⁸, insofar as the latter does not necessarily recognize that the health professional-patient relationship is essentially one of power, and therefore does not provide an effective frame for resolving the ethical dilemmas inherent in such relationships. Furthermore, while patient autonomy is one of the pillars of *principlism* – although not excluded – the patient is not assumed to be the central actor of the clinical encounter. Consequently, the ethical and legal principles underpinning patient rights are not translated into professional practice.

Besides the complementarity of HRPC and the principles of bioethics, by broadening understanding and the scope of the provider-patient relationship, HRPC enable the resignification of the concept of patient safety underpinning more ambitious initiatives to enhance health care quality in its broadest sense, where respect for the human rights of patients and providers is a concrete fact.

The HRPC framework enables clinical practice to be ethically guided by rules encompassing positive and negative imperatives, which makes

solving problems that do not necessarily find a solution in bioethics less challenging⁹. In short, HRPC provide a theoretical framework for arriving at decisions in clinical practice⁶.

Informed consent – an essential element of HIV testing

HRPC encompass a series of rights, including the right to privacy, which is enshrined in the International Covenant on Civil and Political Rights – adopted by the General Assembly of the United Nations in 1966 – and American Convention on Human Rights – approved by the Organization of American States in 1969 – among other human rights treaties. The right to privacy includes the rule that any health care intervention requires patient authorization or agreement, as the expression of consent removes the prohibition on interfering with someone else's body. The protection of personal autonomy – the condition of self-governance according to one's own needs, will and preferences – is thus at the heart of the right to privacy. The right to informed consent – where health professionals must obtain the patient's permission to “interfere” with their body – also derives from the right to privacy. Unlike the right to privacy, the right to informed consent also links with the right to not be subjected to torture or to cruel, inhumane or degrading treatment, as forced treatment or procedures constitute a violation of this right¹⁰.

Informed consent is a communication process involving the patient and health professional that results in the patient's authorization or agreement to undergo a specific medical intervention¹¹. This process involves the provision of information in order to obtain the patient's voluntary permission – without coercion or duress – to undertake any procedure related to their health or body¹¹. Any medical intervention carried out without consent, regardless of its importance, constitutes an interference with the patient's private life and breach of the principle of respect for personal autonomy¹⁰.

Informed consent is directly tied to the right to information, as patients also have the right to be informed about all treatments available for their condition, the examinations and tests they will undergo, and the risks involved¹². The right to informed consent therefore implies the fulfillment of the right to information, as it is assumed that the patient will be informed about the risks, benefits and alternatives, and the right to refuse treatment by withholding consent, as consent

can only exist when the patient is able to refuse consent¹³.

The ethical and legal requirement to obtain informed consent can be waived under the following circumstances: (a) when the patient is incapable of giving informed consent; (b) emergencies in which there is a risk of death and there was no opportunity to obtain patient consent; (c) the patient waives consent¹³. In addition, the right to informed consent can be limited when it is in the public interest, such as public health concerns. Within the sphere of international human rights law, human rights restrictions on public health grounds have been a well-established issue for some time¹⁴. Public health concerns can therefore be grounds for restricting rights under both ordinary and extraordinary circumstances, resulting in the limitation or derogation of certain rights. In this regard, the European Court of Human Rights provided that the right to patient privacy is not absolute and may suffer interference on public health grounds¹⁴. It is important to stress that this does not amount to a balance between the patient's individual rights and “collective rights”. This assertion is erroneous since restrictions amount to the limitation of an individual right in the collective interest, in this case public health. Restrictions on human rights may be justifiable only when they are: (a) provided for and carried out in accordance with the law; (b) based on scientific evidence; (c) directed toward a legitimate objective; (d) strictly necessary in a democratic society; (e) implemented with the least intrusive and restrictive means available; (f) neither arbitrary nor discriminatory in application; and (h) subject to review¹⁵.

The constant evolution of the informed consent process for HIV testing

HIV antibody testing first became available in 1985^{2,16}. The initial goal was to prevent transfusion-associated HIV infection^{2,17}. At the time there was no consensus as to whether HIV screening should be encouraged²². It was only in 1987 that the main implications of a positive diagnosis became evident, with testing being coupled with counseling as a strategy to change behavior and prevent transmission^{2,17}.

It was a time of enormous anxiety about the emerging AIDS epidemic. Fear of discrimination, stigma, and social exclusion haunted the communities most at risk of infection. This fear and the limits of health care at the time provided the background for the initial discussions of the

ethics of HIV testing. While some public health officials highlighted the need for wide-scale voluntary testing, serving as an important complement to counseling and driver of behavioral change, representatives of the groups affected by the infection, especially gay men, saw the strategy differently. For them, testing posed a risk of harm to socially vulnerable groups. Not only was the test harmful but, opponents of the test suggested it was unnecessary for public health¹⁷.

The psychological impact of a positive diagnosis in the context of the absence of therapy, combined with concerns about potential discrimination and stigmatization, and anxiety about the prospect of coercive testing policies shaped the view of activists who sought to protect vulnerable populations to ensure confidentiality and respect for autonomy. Only written informed consent could provide the necessary protection^{16,18}.

However, in the 1990s, with the management of opportunistic infections and emergence of the first treatment options, activists began to question the protective ethical framework grounded in mandatory counseling and informed consent, which some theorists called “exceptionalism”¹⁸.

In 2001, the Centers for Disease Control and Prevention (CDC) revised its recommendations for HIV testing of pregnant women, ushering in the simplification of the testing process. Pre- and post-test counseling were made optional so as not to pose a barrier to testing. Informed consent could be oral and noted in the patients’ medical records. Screening was recommended in clinical settings in which HIV prevalence was high (maintaining the recommendation that in low-prevalence settings testing should be defined on the basis of high-risk behaviors)². In 2003, the CDC modified recommendations in order to simplify the testing process, advocating the normalization of HIV testing, making it a routine part of medical care on the same basis as other diagnostic and screening tests. Counseling was considered desirable, but not mandatory².

Although certain groups were against the removal of mandatory counseling and specific signed consent^{19,20}, in 2006, following the trend towards the normalization of HIV testing, the CDC recommended that testing should be decoupled from counseling and that screening for HIV infection should be performed routinely for all patients aged 13-64 years unless they declined (opt-out screening), further simplifying the consent process².

Lengthy mandatory counseling by overburdened health staff was seen as a barrier to offering

testing^{2,21}. As a result, counseling was no longer required in general HIV screening programs, being considered distinct from HIV testing and recommended as a prevention strategy only for persons with high-risk behaviors².

Routine testing began to be recommended for all patients regardless of risk behavior²² on the same basis as screening for other conditions in normal practice.² By being treated like other screening procedures, HIV testing was “normalized”, reducing stigma and encouraging acceptability²¹.

Also with a view to normalizing testing, the CDC recommended “opt-out” screening, whereby the patient is informed that testing will be performed unless they decline.² Standardized scripts for offering testing included: “We’re offering routine HIV tests to all of our patients. You will be tested unless you decline”²³. Studies have demonstrated an increase in test acceptance using this method²³. However, questions remain about patient understanding of the procedure²⁴ and whether the method involves a certain degree of coercion, resulting in criticism from an ethical point of view¹⁸. In this regard, the recommendations clearly state that HIV testing is not mandatory¹⁸, but rather a voluntary procedure without coercion that should not be undertaken unknowingly².

The imperatives of expanding HIV screening in emergency departments

Since the publication of the CDC guidelines recommending HIV screening in all clinical settings in 2006, there has been considerable public interest in expanding HIV testing in emergency departments. However, because these clinics are sensitive environments that primarily provide urgent and emergency care²⁵, a number of questions have been raised about the appropriateness of these settings for universal screening programs. Overcrowded emergency departments are an everyday reality in Brazil and worldwide and there are concerns that the introduction of screening programs in such a busy environment might interfere with acute care processes.²⁶ Other issues include physical resource²¹, staffing²¹ and time² constraints, lack of mechanisms to ensure the delivery of results²⁷, clinical follow-up², and the costs involved in each potential diagnosis²⁸. In addition, not all health professionals are open to the idea of universal screening in emergency departments and some resist²⁹. Another concern is the physical and mental suffering experienced

by emergency patients who discover that they are infected with HIV³.

However, a number of studies investigating the implementation of universal HIV screening programs in emergency departments show that testing does not affect routine processes and that a number of interventions have been successful^{3,25,26,30-34}.

While recent behavioral-risk screening programs in emergency departments have presented similar results to universal testing approaches – at a lower cost in some initiatives^{26,35} – testing focused on people with certain clinical presentations or behavioral risks has tended to fail to identify many cases of HIV³⁶. Furthermore, only the universal approach has the potential to reduce stigma associated with risk-based testing³⁶.

Vulnerability in the emergency department and the dilemmas of HIV screening

One of the most notable ethical issues arising from HIV screening in emergency care departments is “opt-out” consent, whereby the patient is notified that testing will be performed unless the patient refuses in an attempt to expand testing³⁷. In this regard, offering a test to someone in a poor state of health may be perceived as potentially coercive as they may find it harder to refuse due to their additional vulnerability³⁸.

The fact that many people still decline the test despite the fact that survival gains outweigh the decrements in quality of life resulting from a positive diagnosis may warrant increased investment in educational programs targeting this public³⁷.

Thus, efforts to incorporate screening as a routine part of emergency care should be carefully reviewed to assess whether testing should be offered or not, including the potential limitations of informed consent in these settings given the difficulties of assessing capacity to consent for patients with more critical health conditions and particularly under the pressure of meeting immediate treatment demands³⁷.

Though there is never a good moment to receive a HIV positive diagnosis, some moments may be better than others. With regard to “opt-out” testing, individuals who believe they are not at risk may decide to accept the test either because they tend to follow the recommendations of health professionals, feel awkward declining the test, or are concerned or distracted by the health problem that made them seek care. Thus, they may agree to be tested at a time in their life in which they otherwise would not have opted

to do so if they had known the result would be positive³⁷.

Little is known about the extent to which life circumstances can affect the ability of HIV-positive individuals to assimilate and react adequately to their diagnosis. Moments of hardship, such as losing a job, abusive relationships and legal problems, may adversely affect an individual's ability to take in their diagnosis³⁷.

The provision of potentially distressing information to an already vulnerable person occurs in different contexts in health services, for example when conducting unpleasant tests for rape victims³⁸.

One argument against increasing HIV testing in emergency departments is that the distress and discomfort of having a medical emergency and seeking emergency care may compromise a patient's capacity to consent, thus making these settings inappropriate for testing. On the other hand, however, HIV testing is recommended during labor, which is a moment that generally involves discomfort and pain. Furthermore, the literature also suggests that testing is appropriate for patients with serious chronic illnesses, such as rheumatic disease³⁹ and cancer⁴⁰, those in acute medical units⁴⁰⁻⁴², intensive care units⁴³ and undergoing pre-operative assessments⁴⁴, and psychiatric inpatients⁴⁵. In African countries, where the prevalence of HIV in the general population is high, there are even initiatives that offer testing services to persons visiting funeral homes³⁸.

An argument for testing in emergency care departments is the moral duty to protect third parties⁴⁶. In this regard, patients participating in a study assessing a testing intervention in emergency departments suggested that HIV testing was a public responsibility, both in relation to public health – to reduce transmission – and to health system costs incurred by the state⁴.

Informed consent and the human rights of patients: options in the real world

This section explores different contexts of consent for HIV testing: presumed consent, consent initiated by nurses or other health professionals, consent during triage, consent during blood collection for other tests, and self-testing.

Presumed consent

Health professionals should discuss all diagnostic and therapeutic interventions with patients. However, some authors suggest that

consent can often be implied, as in the case of low-risk procedures such as blood tests²⁷. Presumed consent can be understood as an implied agreement by which the patient, by supplying urine or blood, agrees to the routine testing of these materials¹⁶. This type of consent is inconsistent with the right to the self-governance of health care according to one's own will and preferences, because the patient may not wish to undertake a specific test at that moment in their life. It is also important to note that the patient has the right to be informed about all tests and their consequences – even when they are “routine”.

It is argued that potentially risky interventions require explicit informed consent and that for HIV tests that are not blood tests, but rather procedures involving patient cooperation, such as colorectal cancer screening or mammograms, consent is an unequivocal requirement^{16,27}. In emergency care settings, this requirement includes invasive procedures such as lumbar punctures or central venous access. Essentially, obtaining a blood sample to perform the HIV test does not pose any physical risk to the patient and the benefits of a diagnosis are widely documented²⁷.

As mentioned above, the requirement of informed consent for HIV testing is grounded on the patient's right to conduct their life as they see fit. This includes choosing when and how to take the test, given that the result could have a significant impact on the patient's life. Thus, the patient alone should decide if he/she is ready to shoulder that impact. A positive HIV test can lead to the loss of support from family or friends, depression, relationship breakups and a series of other problems that can have a profound impact on the patient's life²⁷.

The argument that testing has benefits is not enough to forgo the patient's right to decide when and how to take the test. The benefits of diagnosis should be cited to enable the patient to take an informed decision. In the case of adults, what comprises a benefit should be decided by the patient.

In keeping with the HRPC, some scholars reject the use of the term “routine” to justify testing without the patient knowing. HIV testing should not be performed under the conditions of presumed consent that governs various other medical tests¹⁶. Complete routine HIV testing without the patient's prior knowledge fails to meet ethical standards and thus violates patient rights⁴⁶.

Informed consent initiated by nurses or other health professionals

Despite continuing education, performance feedback, and innovative methods to remind physicians to order the HIV test in emergency departments, studies have shown that some screening programs have poor testing rates. The study in question showed that while some physicians did not order tests because they believed screening in these settings to be inappropriate, the majority reported simply forgetting to order tests in busy environments³¹. Another reason for low testing rates is the difficulty in getting physicians to prioritize preventive care in the face of other more urgent patient needs³⁰.

An alternative is nurse standing orders. Nurses perform various tasks in different clinical settings, meaning that assigning the responsibility for testing to these professionals makes a lot of sense³⁰. Emergency department screening initiatives in other countries in which nurses obtain informed consent – generally in the triage/intake process – and order the test³¹ from the laboratory or perform rapid bedside tests have been shown to be successful³⁰.

Even in places where the flexibilization of HIV testing has been historically constrained, recent legislation authorizes other health professionals besides physicians to obtain informed consent for testing, as is the case in New York⁴⁷.

Thus, HIV testing performed by nurses or other health professionals constitutes an effective measure for ensuring informed consent and increasing testing while keeping the patient at the center of care.

Informed consent during triage

All patients go through triage, making it a good option for incorporation into HIV screening programs. Initiatives in other countries where informed consent for HIV testing is decoupled from the medical appointment and obtained by nurses during triage have been shown to be successful. The test can be performed in the triage area before the patient is seen by the physician using the rapid testing method³² or is automatically authorized in the blood tests requested during the medical appointment³¹. As mentioned above, broad consent for blood tests fails to meet the principles of the right to informed consent, which requires health professionals to provide adequate and accurate information to patients about what they are consenting to. Likewise, in-

formed consent during triage should be given careful consideration because the patient may potentially be distressed and require urgent health care. Thus, when adopting this approach it is essential to have an adequate area that provides a welcoming and comfortable environment in which the patient can be properly informed about the tests that are being requested.

Consent during blood collection for other tests

Various recent international studies have investigated electronic medical record-based initiatives using systems that issue an automated testing prompt for emergency department and in-patients^{25,34} during medical assessments and at other moments during the routine of other health professionals, such as triage and blood collection^{25,33}.

In a screening program implemented in an emergency department, the electronic medical record captured prior HIV testing. For patients without a prior test, the system issued an automated prompt recommending an HIV test when ordering a blood test. The nurse was then instructed to obtain opt-out consent during blood collection²⁵.

As with consent during triage, it is essential to have an adequate area that provides a welcoming and comfortable environment in which the patient can be properly informed about the tests that are being requested.

Self-testing

Rapid testing can be used in all the above settings, either “*in situ*” during triage or on patients under observation or in-patients – generally performed by nurses – or with blood samples sent to the laboratory, being performed by the laboratory staff. Despite providing swift results, rapid tests have the disadvantage of taking up staff time and therefore require greater staffing.

Self-testing, where the person performs the HIV test, is used in various countries around the world⁴⁸. The test can be done at home or *in situ* during triage with the help of nurses while the patient is waiting to be seen by the physician⁴⁹.

There are diverging opinions on the ethical aspects of self-testing. Arguments against the method include the following: antiretroviral therapy is not readily available in all countries, potential risk of coercive testing by partners; testing outside the health system can have negative

consequences related to difficulties in finding appropriate treatment and retention in treatment⁵⁰; cost may limit access when the test is not available on the public health service; and false-negative results during the window period may lead to a false sense of security⁵¹.

However, self-testing can promote personal autonomy because it allows patients to dictate the circumstances under which they perform the test and there is no strong ethical objection to this method⁵². Furthermore, the modality is widely acceptable, especially among high-risk individuals, and empowers users, thus helping to normalize testing.⁵¹ In addition to high acceptability and accuracy, individuals are able to test anonymously, thus reducing the barrier of stigma⁵¹.

In the HRPC framework, the essential question of timely access to care includes offering services in such a manner that access does not result in discrimination and stigmatization of the most vulnerable populations. Self-testing is therefore a step forward in establishing patient-care system relationships that cement the right to health with respect for the person’s dignity and integrity.

Consent and sharing decisions: a necessary future

The HRPC theoretical framework reaffirms the need to obtain informed consent to perform HIV testing⁵³. Indeed, there is no ethical or legal justification for restricting patients’ right to make their own significant life choices. Arguments concerning the benefits of early testing should be weighed up by the patient, who, after being properly informed, should be the sole decision maker when deciding which tests to do and the appropriate moment to do them. In addition, recognizing the importance of increasing HIV testing in emergency departments does not mean that the right to informed consent can be restricted, but rather that other measures can be implemented, such as informed consent initiated by nurses or other health professionals.

Normalizing “routine” testing without informed consent, even when oral consent is obtained, reveals a paternalistic culture in which health professionals make decisions on behalf of the patient allegedly based on the concept of good. Thus, despite a robust bioethics theoretical framework for the requirement of informed consent, the HRPC approach is needed to ground this requirement in respect for fundamental human rights within a universal legal framework. It

is therefore possible and desirable to conciliate the expansion of HIV testing, albeit in sensible environments like emergency departments. Certainly, the act of giving consent will only achieve true legitimacy when ethical principles are re-

spected and understood within a broader human rights framework for both patients and health professionals, who, after providing the best available information, should share the decision over whether or not to give informed consent.

Collaborations

RJ Moura contributed to the article conception and design, manuscript drafting, critical review and final approval of the manuscript. GAS Romero contributed to manuscript drafting, critical review and final approval of the manuscript. A Albuquerque contributed to the article conception and design, manuscript drafting, critical review and final approval of the manuscript.

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