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### Article

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## **ABSTRACT**

The use of self-testing as part of a national screening program for HIV infection in resource-poor environments may have a number of attractions, including ease of accessing difficult to reach and / or isolated populations. However the presence of such technologies is relatively early stage in terms of use and impact in the field.

A principle-based approach, that recognizes the fundamentally utilitarian nature of public health combined with a focus on autonomy, is used as a lens to explore some of the ethical concerns raised. The conclusion reached is that at this point in time, on the basis of the principles of utility and respect for autonomy, it is not ethically appropriate to incorporate the use of unsupervised self-testing as part of a public health screening program for HIV in resource-poor environments.

**Key words:** unsupervised self-testing for HIV; public health screening; ethics; autonomy; utility.

## **INTRODUCTION**

This paper considers the use of self-testing for HIV infection (HIVST), as part of a national screening program, in resource-poor environments. It explores how an adequate conception of autonomy might impact an ethical analysis of HIVST in such environments. HIVST in this context refers to the use of test kits such as that approved by the FDA in 2012 (1), available for purchase or distributed free of charge by public health authorities, in order to test for HIV infection in the privacy of one's own home or other similar settings. Both supervised and unsupervised self-testing strategies have been identified in the literature (2). In terms of the ethical concerns raised in this paper it is unsupervised self-testing that is the main focus of attention. In this self-testing process there is no required link to either pre or post-test counselling or to treatment and care.

The increased availability of anti-retroviral therapy (ART) has, in recent years, led to a massive scale-up of screening for HIV infection internationally. The question for many governments is not whether there should be a scale-up of testing for HIV but how to do so in the most effective, efficient and equitable manner possible (3).

In countries with a high prevalence of HIV, where both a sophisticated network of medical laboratories are lacking, and where it is very difficult to access remote populations,

governments and public health policy makers are turning to HIV self-testing as a means of vastly increasing the reach of screening programs (4, 5). Self-testing devices are portable, easy to use and provide rapid results (6). Due to improvements in relevant technology self-testing has also become more effective and evidence suggests that it is more attractive than traditional screening methods to certain groups (2). Self-testing is also likely to help in reaching both remote and hard to access groups such as sex workers and MSM (6, 7).

Given the imperative to scale up screening and the potential impact of ART in both reducing viral load and making a carrier less infective (8), it seems reasonable to argue for the inclusion of all accurate approaches to screening for HIV to be employed in public health screening programs. In addition convenience and acceptability (2) would seem to underline the benefit of HIVST as an important strategy in such screening programs, particularly in resource-poor environments such as sub-Saharan Africa.

Millions of people are currently infected with HIV, a significant percentage of who are unaware of their infected status (9). These facts, combined with an increased availability and effectiveness of ART (8), make up-scaling of screening imperative. A combination of factors has led a number of governments and policy makers in resource poor environments to look to the use of self-testing as part of public health screening programs for HIV.

However I argue that given the profile of significant groups in the infected populations, and the context in which they live, the use of unsupervised self-testing is ethically inappropriate from the perspective of both principles of utility and respect for autonomy.

The principle of utility, the core principle of Utilitarianism, requires that in any situation of moral decision making moral actors should strive to do that which will increase the good (defined variously as happiness, benefit and so forth) over the bad (pain, burden). In decision making in the public moral sphere, for example in issues of resource allocation, it is frequently suggested that the principle of utility is a very attractive, if not the only viable moral principle from which to operate (10). The principle of autonomy, on the other hand, focuses on the individual and the individual's right to self-determining choices and decisions. This principle has gained increasing importance in the sphere of personal medicine throughout the 20<sup>th</sup> and 21st centuries; with some medical ethicists arguing that autonomy is the primary principle of biomedical ethics (11, 12).

In terms of the use of well established self-testing devices such as pregnancy, cholesterol and prostatic antigen (PSA) tests for example, the demand and indeed the justification for the development and use of such tests is intimately linked with notion of personal autonomy and the individual's right to both information regarding and right to participate in decisions affecting their health and life-style (13, 14). The use of self-testing also fits well with current policy and rhetoric regarding individual responsibility for one's health and the onus on individuals to participate in their health care and in health service delivery (14, 15).

Experiences to date with self-testing for screening purposes has, however, raised concerns in a number of areas including the following: (a) inaccurate claims with regards to the

efficacy of PSA to improve outcomes for prostatic disease (16), (b) the promotion of culture of the worried well (17), (c) contribution to psychological distress due to false positives (18), and (d) the “creation” of perceived need for self-testing for HIV for purely commercial reasons (19).

Such concerns should be borne in mind when considering the ethics of self-testing for HIV in resource-poor environment; where regulation and oversight may be even more difficult to achieve than in the context of Western, personalized health care where self-testing tends to have its developmental roots.

#### **ETHICS AND HIVST: ISSUES OF POPULATION PROFILE**

However, in addition, there are a number of issues regarding the profile and context of those infected that seems relevant in an analysis of how best to scale up screening (and linkage to care and treatment) in an ethically acceptable manner.

Approximately 25 million people in sub-Saharan Africa are currently living with the HIV virus. There are a number of high risk groups such as sex workers and men who have sex with men (MSM). In many resource-poor countries however women and girls are at particularly high risk of infection. Females account for 57% of all those infected in this region (9). As far back as 2001 Van Niekerk commented: “The situation in Africa has shown definitively that AIDS flourishes most demonstrably in a society where women are particularly vulnerable” (20).

Significant numbers of those infected are unaware of their HIV status (9). Identifying those who are infected and linking them with support and treatment is crucial to these individuals’ survival, and to the survival of their sexual partners.

Resource-poor environments impact seriously on societies' ability to protect human rights; as articulated, for example, in the UN Declaration on Human Rights (21). It is clear that resource-poor environments impact the life expectancy, living conditions, nutritional status, disease patterns, choices, security and life trajectory of the poor living in these environments.

Thus in engaging with individuals and populations in resource-poor environment, recognition of the socio-cultural embedded nature of human existence is fundamentally important. The options open to individuals and groups may, at times and in certain circumstances, be very limited.

The role and status of women, as an example, in many such environments and societies, mean that women's dignity as human beings is constantly in danger of being undermined or denied. Women may be directly discriminated against in national legislation, and, perhaps more commonly in the norms and mores present in traditional societies (22, 23). They are both directly and indirectly discriminated against in tradition, cultural and social practices and norms (24-26). In such societies / groups females may be considered the property either of their parents, or, on marriage, their spouse. They have less access to education (9, 25) and thus are much more likely to be dependent on males for financial security (25-27). This results in freedom of choice, movement and the ability to exercise autonomy, as understood in 21<sup>st</sup> century Western societies and health care systems, being severely curtailed.

The need for reform, in terms of the role and status of women, is at one level well recognized and, for example, countries such as South Africa have brought in new legislation to assist such

reform (28). However when the power relations among those involved in the debate (gender relations and the role status of women in society) is both the context and the subject matter, open discussion is likely to be severely hampered and actual reform at best very slow in coming (24).

Thus in the context of HIV infection in many resource-poor environments, women and girls, like sex workers, MSM and domestic workers, are particularly vulnerable populations, subjected to sexual and other forms of violence and injustices. There is evidence that due to their social status and lack of legal protection these groups are more vulnerable to mistreatment and coercion. Women, for example, are more vulnerable to violence, abandonment, destitution or death at the hands of their partners, families and communities (24, 26, 29, 30). There is also evidence that women testing positive for HIV suffer greater violence post diagnosis (31).

### **Ethic and HIVST: Issues of Utility**

Availability and inclusion of unsupervised HIVST as part of public health measures, in such contexts, is likely to increase these vulnerabilities and expose individuals to coercive testing. Vulnerabilities may be increased due to physical, psychological and social power imbalance and lack of personal control over access to one's body by virtue of disempowerment, dependency and lack of or inability to enforce structures, policy and processes protective of human rights. Increased vulnerability leads to increased burden in the lives of these individuals.



Incorporating HIVST as part of a public health screening program, from the perspective of the principle of utility – the fundamental principle of public health ethics (32) – on first view seems to make good sense. If HIVST, as a screening approach, is likely to reach more people, and be especially useful in reaching those in remote areas or difficult to access groups such as men, sex workers and MSM, then it seems that increased benefit over burden is achieved. It is also the case that the increased convenience and acceptability and the lack of a requirement to subject oneself to what may be seen as unnecessary or ineffective counseling further reduces the burden on individuals.

However if in reaching these remote and difficult to access populations, or individuals who wish to avoid further education or counseling, in addition to bringing the benefit of screening – and thus knowledge of the HIV status of tested individuals – some other individuals are in danger of being coerced into accepting testing, or are tested without being linked into care and treatment, or are vulnerable to abuse, violence abandonment or destitution, then the balance of benefit over burden can swing in a negative direction.

On the utilitarian calculus this is, at a basic level, simply a matter of numbers – each individual counts as one and only one. Thus although, for example, men are a hard to access group in terms of screening for HIV and men also seem to prefer self testing(2) to provider initiated testing and counseling (PITC), only 43% of all those currently infected in Sub-Saharan Africa are male. All other things being equal self-testing should be encouraged in order to (a) encourage more men to be tested and (b) enable more men to become aware of their HIV status as a first step to accessing treatment and care. However all other things

are not equal. Certain groups may be at increased risk of coercion and violence or other forms of abuse if self-testing is introduced as part of a public health screening program. Some of those at increased risk of coercion, violence and abuse are women. Some of them are sex workers, many but not all of whom are women, some are MSM, some are migrant and domestic workers, who may also be men. Thus the individuals at risk are both men and women – this reduces the overall number of men in the population who may only benefit from the introduction of self-testing as part of a public health initiative.

As suggested above screening is not a neutral activity (33). It has potentially life-changing (and life-endangering) consequences for the individual screened and many in their intimate circle. It behooves health workers, policy makers and governments engaged in encouraging and implementing such screening programs to bear the potential consequences clearly in mind. A relevant issue here is ‘Does the harm of a life threatening infection override these consequences, and who decides?’ If self-testing opens the door to readily available treatment and care then it seems that benefit prevails. However if treatment is unavailable to even some, the risks of breeches of personal autonomy (including privacy, consent and confidentiality), violence, abandonment and destitution may outweigh the possible benefits of screening (2, 34).

Thus a relevant question is ‘Does the benefit to burden calculation suggest significant risk of increased burden to vulnerable individuals?’ Given that we know that more women and girls are infected, for example, and given that we also know that such groups are particularly

vulnerable in resource-poor environments where social norms and legislative structure do not, or cannot, offer adequate protection of basic rights, HIVST does appear to bring increased risk. An acknowledgement of the risks of testing for HIV could be argued to underlie the omission to collect test results of a high percentage of pregnant women, who are routinely tested for HIV in antenatal clinics (35) and/or their reluctance to disclose positive results to their partners (30). It is the case, due to routine testing of pregnant women, that more women have access to HIV testing (and to treatment) than other vulnerable groups; such as migrant and domestic worker and MSN. However some of the risks of screening may be very similar for these groups.

In order to justify HIVST in such a context it is necessary to show that despite such increased vulnerability there is nonetheless, and in fact, such a substantial increase in the benefits derived from the use of HIVST, that at worst it balances out the increased burden of vulnerability and at best results in a positive balance of benefit. If there is clear evidence of a coherent and viable plan to link those who test positive, including those members of groups exposed to increased vulnerability, to care and treatment then on utilitarian grounds it would still be reasonable and justifiable to argue for the inclusion of unsupervised HIVST as part of a public health screening program. However at this point in time there does not seem to be evidence of either a coherent or a viable linkage program, nor a focused discussion with regards to whose responsibility it is to ensure such a linkage program. If this is an accurate description of the current state of planning with regards linkage of infected individuals to care and treatment, it seems ethically unacceptable to potentially increase the burden of vulnerability, by integrating HIVST as part of public health screening, among that significant

percentage of the population already exposed to the burdens of poverty, gender, power deficits and HIV infection, in resource poor environments. Thus, despite the obvious screening potential of HIVST, on utilitarian grounds an argument can be made against the ethical appropriateness of rolling out unsupervised HIVST as part of a public health screening program. This is particularly the case when there is evidence of effective home based testing initiatives, which apparently include the benefits of easier access to remote populations, increased couples testing and good linkage and uptake of care and treatment (2, 36 - 38).

Recognizing the reasonableness of concerns regarding coercive testing and the potential aftermath of a positive result is important in understanding the ethical implications of HIVST. If it could be determined that control over HIVST would remain with the individual, and that the individual once testing positive could access treatment with relative ease, then the potential utility (benefit) of HIVST increases. This is particularly the case in light of evidence that many groups including men, MSM, and couples prefer the convenience and privacy offered by HIVST (2, 38); but also clearly articulate a majority need for continued access to counseling and information (37). Thus once again the context in which HIVST is introduced and used is a very important factor in determining the ethical acceptability of integrating HIVST as part of a public health screening program. It should also be noted that ethical concerns regarding the integration of HIVST as part of public health measures does not automatically rule HIVST out in the context of personal health care. This will be discussed further below.

## **RESPECT FOR AUTONOMY**

However a further argument against HIVST comes from considerations of the principle of respect of autonomy, particularly when a conceptualization of autonomy in terms of relational autonomy (39 - 41) is used.

Autonomy is normally defined as a multi-faceted concept including the ability to make decisions for one's self, to exercise choice, to deliberate over options, self-determine and self-govern. The concept has evolved from its Greek origins via influences from Immanuel Kant and John Stuart Mill, with respective emphasis on deliberative self-regulation and the ability to follow one's preferences, to current libertarian conceptions of autonomy.

Libertarian conceptions of autonomy, as freedom from constraint and freedom to choose, is growing in Western society and is linked, within the context of health care, with consumerist free-choice (42).

However there is a growing critique of this conception of autonomy and its application within health care (7, 14, 43, 44). A richer conception of autonomy recognizes that human beings do not exist / flourish in isolation. An integral part of being human is being part of and intimately connected to other people. It would therefore seem that in respecting our ability and right to exercise our autonomy, the socially embedded nature of our being should form part of any adequate notion of autonomy. Conceptualizations of autonomy may not be divorced from the cultural context in which, for example, issues of HIV screening (including the process of HIVST) arises. The cultural context sets the scene for a more relational

perspective highlighting, for example, societal implications of screening. Thus, while recognizing that the right to give informed consent is an important practical application of respect for autonomy, so also is the recognition that in certain, specific circumstances such as illness, serious stress, poverty and relative powerlessness, the exercise of one's autonomy depends not only on the negative rights to non-interference but on positive rights of adequate support, assistance and protection. In this vein it can be argued that the principles of respect for autonomy and justice are connected (44).

In most theories of autonomy two basic requirements must be fulfilled for autonomy to be said to exist:

1. Liberty (freedom from controlling / coercive influences) and
2. Agency (capacity for intentional action) (10)

Respecting autonomy requires not only an attitude of respect for the individuals involved, it requires the taking of 'respectful action'. It is more than non-interference; it may require developing and supporting the other's capacity for autonomous choice by removing fears and conditions that undermines autonomous action. It requires us not only to not use others as means to our own ends, it requires us to assist them in achieving their ends (10).

Within the context of HIVST in resource poor environments two potential autonomy-related issues that may emerge are (i) issues related to informed consent and (ii) fears of violence and criminalization following a positive result. With regards to informed consent the WHO guidelines on HTC, for example, indicate that individuals must be informed of the process of HTC, of the follow-up services available should the initial test prove positive and of the

individual's right to refuse testing (45). In a context of the roll out of unsupervised HIVST the possibilities of ensuring such information provision consistently need to be examined carefully. Should such provision be possible concerns regarding the ethical implications of unsupervised HIVST diminish significantly. The image of the individual collecting and administering a self-test in private, at a conducive time, to check his or her status rather than travelling to the nearest health facility for such testing, sometimes a considerable cost and inconvenience, seems to make clear sense. The image of the same individual collecting four such kits, taking them home and requiring a partner and two domestic workers to take the test with them, without any requirement to provide information or follow up conjures up a different picture and set of concerns.

From the perspective of the relational reality of human life, basic human sympathy and morally decent behavior it would seem incumbent that infected individuals divulge such information to their sexual partners. The implication for partners (and offspring) in the HIV infection scenario is, without question, potentially life threatening. However where the risks to the divulging individual are high, in terms of stigmatization, abuse, violence or criminalization such risks mitigate against supporting our relational existence and, immediate-term concerns of self-protection and survival, risk overriding the moral imperative to disclose. The individual may even avoid confirmatory testing on the basis that until such confirmation is received the actual HIV status of the individual is unknown, thus reducing feelings of guilt or responsibility; such an approach could be seen to mirror the refusal of many women to collect test results following pre-natal screening (35).

A conceptualization of autonomy, from the liberty element through to the idea that, in certain circumstances, we are morally obliged to help people achieve their ends, seem very important in considering the ethical acceptability of the inclusion of unsupervised HIVST in public health screening programs. It seems that this is where there is a difference in enabling individual choice through access to HIVST by approving certain devices for individual use at personal cost – such as is currently the case with pregnancy and cholesterol test kits - and integrating HIVST as part of a public health screening program. If there are accurate testing devices available, and their sale and use (in terms of safety and accuracy) can be assured, arguments supporting individual autonomous choice suggest that access to such devices should be facilitated, not prevented. This, broadly, as I understand it, is the argument developed by Allais et al in the current issue.

However it seems that integration of HIVST as part of a public health program puts more onus on policy makers and practitioners to ensure public benefit from such a move. Such benefit should, as argued above, at worst neutralize any increased burden attendant upon HIVST and at best increase overall public benefit. Firstly there is the question regarding the existence of individual liberty / liberty rights for members of the vulnerable groups of concern in this paper – sex workers, many women in resource poor environments, migrant and domestic workers in such environments. The restrictions on or basic lack of liberty of persons in such situations has significant implications for the ability of such individuals to exercise autonomy and autonomous choice or to autonomously refuse HIVST. Secondly on the basis of the liberty issue (or absence thereof) it is possible to argue that if HIVST is introduced into public health screening program either (i) liberty and autonomous choice /



decision making must be assured - a very difficult proposition in the environments in question, though supervised HIVST appears to hold much promise (36-38); or (ii) the introduction of HIVST in such contexts is ignoring the rights and dignities, and autonomy capacities of the individual members of the vulnerable groups of concern. One is thus directly infringing the principle of respect for autonomy and using these vulnerable individuals as means to others ends.

## **CONCLUSION**

The urgency to scale up diagnosis and treatment of HIV infection is clear. Effective home based testing and counselling for HIV is possible, as is supervised HIVST (2, 36 -38). Both of these testing strategies appear to offer efficient and effective ways to make screening for HIV highly acceptable and convenient and linkage to care possible. However there is little evidence to date that this is the case for unsupervised HIVST (2). The particular focus of this paper is on the ethical appropriateness of the introduction of unsupervised HIVST in the context of resource-poor environments, where the lot of women and girls, migrant workers, domestic workers, sex workers and MSM may be particularly precarious. These vulnerable groups form a significant part of the populations where HIVST is being considered for public health screening purposes. On utilitarian grounds we must be able to show that there will be increased benefit over burden to this large, vulnerable population, in the roll out of unsupervised HIVST as part of a public health screening program. On autonomy grounds we further must be assured that both the liberty and agency of the vulnerable individuals of

concern are adequately protected in such a public health initiative. Then and only then, it is argued, should unsupervised HIVST become part of public health screening.

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