HIV, trauma and the emergency departments: The CDC opt-out approach should be adopted in South Africa

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Background. Trauma is the fourth burden of disease in South Africa (SA). The risk group is the same as that for HIV/AIDS. The Centers for Disease Control and the World Health Organization promulgated the opt-out testing system 10 years ago and several high- and lower-middle-income countries have adopted this approach.
Objective. To review the feasibility of implementing the opt-out system in SA emergency departments.
Methods. We examined the clinical, economic, practical and patient/provider perceptions concerning the scientific and ethical aspects of the opt-out concept.
Results. Patients were generally positive about the opt-out system and the overall test rate and disease identification rates were better than with other systems. Although initial costs may increase, the long-term cost benefit and prevention of transmission, due to linking to care, make this option attractive.
Conclusion. The opt-out option for patients presenting to emergency departments with an acute life-threatening illness or trauma, and for those in critically ill states in an intensive care unit, is justifiable based on international and regional practices. This also has the potential to advance early highly active antiretroviral therapy and reduce treatment costs and the disease-adjusted life years for HIV management and trauma critical care. SA should adopt an opt-out testing system instead of the current tedious opt-in system.

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Despite strides in combatting HIV worldwide, South Africa (SA) has the largest number of new HIV infections in the world, with about 1 000 new infections occurring each day among adults aged 15 - 49 years in 2012.[1] Early detection and effective HIV treatment extends life expectancy, improves life quality, and reduces HIV transmission, making it a cost-effective public health intervention.[2] The National Strategic Plan on HIV, sexually transmitted infections (STIs) and tuberculosis (TB) 2012 - 2016 aims to reduce new infections by at least 50%.[3] However, the prevalence of infections across provinces ranges from 5% to over 14% in KwaZulu-Natal and the Eastern Cape.[4]

HIV prevalence is highest in males aged between 15 and 49 years who engage in high-risk behaviours (in the order of 30%).[4] This same population is also at a higher risk of acute illness and injury and therefore more likely to present to the emergency department (ED) for care. In SA emergency care is a basic human right enshrined in the constitution.[5] EDs provide unprohibited access to care, to large volumes of patients for a short period of time. The ED population tends to be younger and is less likely to access primary healthcare (where most screening occurs). However, EDs remain underdeveloped in the healthcare system and play no role in the HIV epidemic. High rates of unrecognised HIV infection persist in the ED and therefore provide an opportunity for testing and linkage to care.[6]

Despite many longitudinal programmes related to highly active antiretroviral therapy (HAART) and linkage to care in SA, the HIV epidemic falls far short of The Joint United Nations Programme on HIV and AIDS (UNAIDS) '90-90-90' target for HIV-infected individuals, (i.e. by 2020 90% of all people living with HIV will know their HIV status, 90% will receive sustained antiretroviral therapy and 90% will achieve viral suppression). About 36% of patients admitted to EDs have undiagnosed HIV infection; EDs may therefore be a unique avenue to develop and implement an HIV testing strategy.[7]

In 2006 the US Centers for Disease Control (CDC) issued a new directive[8] for the opt-out approach to the routine testing of HIV in any population in the ED whereby opt out-testing would be: routine for all patients aged 13 to 64 years unless the prevalence of undiagnosed HIV infection in the patient population is documented to be <0.1%, and applied to all patients initiating treatment for TB and patients seeking treatment for sexually transmitted diseases, irrespective if known or suspected to have specific behavioural risks for HIV infection. Testing should be an opt-out approach (patients are informed that testing is going to be done unless they decline); screening should be incorporated into the general consent for medical care; and separate written consent and prevention counselling should not be required with HIV diagnostic testing or as part of HIV screening programmes in healthcare settings. Reasons for the opt-out approach include: by integrating opt-out screening into general consent, the screening process is streamlined and routinised; and patients may perceive this as being less stigmatising because they are not singled out for testing.

Studies examining the implementation, effectiveness, patient satisfaction and overall acceptability of the opt-out concept, have since been published. Such opt-out testing is not restricted to the USA and other high-income countries (HICs), but given similar recommendation from the World Health Organization (WHO). In 2007 it was expanded to several low- and low-middle-income countries (LMICs).[9,10]

Methods

A literature review was performed using Medline and Google Scholar with the search terms 'opt-out' and 'emergency care' or 'trauma'. Articles were reviewed to determine their relevance to the following aspects of opt-out testing in the ED: patient acceptance, patient satisfaction, provider satisfaction, the overall uptake and challenges faced, and ethical issues.

Results

HIV testing in LMICs

In Botswana opt-out testing has been successfully adopted with high community uptake.[11] SA legal minds suggest a change in the view about counselling prior to testing, asserting that the special protocols and procedures for HIV testing and diagnosis reinforced 'the internal dimension of stigma' that had prevented many from taking a test.[12]

Numerous studies show HIV prevalence in EDs is high. In Kenya an implementation pilot study reported that 97% of patients offered testing assented, with a 22% HIV-positive rate. Of the positive group, 82% were compliant with treatment at subsequent follow-up.[13] In Uganda, a HIV prevalence of 50% was demonstrated by testing every sixth ED patient.[14] Of these patients 83% were previously unaware of their HIV status.[15] In Guyana, a 30% HIV prevalence in ED-tested patients was found.[16]

India has the second largest cohort of HIV disease after Africa. A study from Northern India demonstrated that opt-out testing was feasible and necessary with a 2% HIV-positive rate. It included neurosurgical emergency cases, as 'these pose higher risk to the surgeon'.[17]

Opt-out testing acceptance

In Uganda 95% accepted testing in the ED when offered opt-out testing by a provider.[14] Of 233 patients who were offered HIV testing, 99% supported HIV testing in the ED and 86% believed testing would improve linkage to care.[15] Using a closed-question survey with a convenience sample of patients in the ED,[16] out of 343 patients interviewed, 75% were amenable to opt-out testing if offered in the ED. Patients >50 years old, females, and those who had not been previously tested were more likely to refuse hypothetical HIV testing. The two most common reasons for declining were, recent HIV test (85%, 95% CI 74.0 - 91.4%) and not considered a risk for HIV/AIDS (83%, 95% CI 73.0 - 90.4%). In this study >30% of patients had never been tested for HIV, with 40% reporting receiving all healthcare in the ED. Fear, stigma and embarrassment (19%, 11.7 - 30.4%), rejection (30%, 20.3 - 41.5%), and being afraid (21%, 12.7 - 31.8%) were also reasons for declining hypothetical HIV-based testing.

Acceptance of the opt-out concept by potential patients varied worldwide from 53% to 97%[13,16,18-22] with refusal rates in an American ED decreasing from 47% to less than 26%, as people became accustomed to it over time.[19] A randomised controlled trial (RCT) of 48 000 ED patients in the USA randomised patients to one of the three arms (opt-in, active choice, and opt-out): 38%, 51%, and 66%, respectively, supported opt-out consent as being superior.[23] A 2011 study utilising comparative time-sequencing found a 78% uptake of HIV testing in the opt-out group compared with 63% in the traditional counsel-and-test method.[20] Rates of acceptance approaching 86% were found in the Deep South of the USA, where the HIV prevalence and TB rates are the highest.[21] The positive feasibility study of the opt-out system led to calls for its expansion to all EDs in the USA.[22] Three groups of patients refused testing:

- those previously tested positive
- previously tested negative
- those who did not consider themselves at risk.[16,19]

Conversely, a study in Singapore was unfavourable for opt-out testing, with only 21% permitting testing.[24] The refusals were largely from older patients and from Chinese citizens who mentioned fear of receiving a positive result as a reason, which may reflect a cultural variance of the acceptability of opt-out testing.

In California patient perceptions and satisfaction were assessed during opt-in and opt-out periods.[25] No difference was found in the attitudes and feelings toward either type of testing. However, the opt-out method had a higher overall uptake. Patients did not report feeling coerced to test and maintained their autonomy in deciding whether to be tested, including the opt-out system. Preserving the patient's perception of autonomy with opt-out HIV screening is important because this has been cited as a major concern with the concept in the past.

Assessing patient perceptions of opt-out testing at a major trauma centre in Alabama,[26] patients overwhelmingly reported support for testing and identified the access to increased knowledge (41%), prevention of further transmission (12.5%), test availability and convenience (11.8%), along with potential access to treatment (4.9%) among the advantages of the opt-out approach. Fear and denial of HIV status as a reason to avoid testing was reported by <5% of patients.

Of 34 patients, from varied backgrounds, polled at a public teaching hospital in New York about their understanding of, beliefs about and reaction to opt-out testing in the ED,[27] some lack of understanding of the option to opt out was found, but they were generally in favour, citing the potential health benefits as the main reason to support the opt-out process. The main confusion was that participants incorrectly assumed that they would face mandatory testing, rather than having the option to refuse, especially if not of decision-making capability.

Opt-out testing and HIV prevalence

In Denver, Colorado,[28] an HIV prevalence of 2% was found when de-identified discarded blood specimens tested anonymously in a cohort of 600 patients who had opted out (declined testing), compared with a 0.75% prevalence of HIV infection in those who opted in (accepted testing). The relative risk of positive tests was high (2.74) in this patient cohort, compared with those who accepted testing. A similar result was found in 2015 in a concordant identity-unlinked study in parallel to an opt-in rapid oral-fluid HIV screening programme in 3 207 patients. They found an HIV incidence of 1.3% in those who declined testing compared with 0.4% in those who accepted testing (p=0.077).[29]

Cost-effectiveness

In a public-funded health system the cost-effectiveness and therefore the longitudinal feasibility is an important consideration. Only one study in Denver, Colorado in the USA, a relatively low-incidence community, has reviewed this aspect of the opt-out programme. Their opt-out programme was more expensive, yet did almost triple the yield of new HIV diagnoses, with a much higher overall testing rate

(25% v. 0.8% of those given the options to either opt-out or opt-in, respectively). The costs were mainly those of test kits (USD 9.50 each, amounting to over USD 70 000), start-up, computer services and staff costs (USD 60 000 v. USD 30 000) and sundries used (due to the larger number of tests, not an actual increase in unit costs).[30]

The potential cost-savings and knock-on transmission reduction, due to early diagnosis, are difficult to determine. This aspect of social justice is also an important consideration. Addressing this, a study demonstrated that >40% of known HIV cases in care at the time could be identified and that early referral led to better care linkage, with over 90% care inclusion in their cohort.[31] They found that it is cost effective as it costs less than USD 10 000 per disease-adjusted life year (DALY) saved. Any saving of less than USD 50 000 per DALY is considered a cost-effective intervention.[31] This is also likely to be positively influenced by the modern 'fourth-generation' rapid test kits currently available for use in the ED, where almost 25% of newly diagnosed cases would have been missed with older test kits.[32]

Discussion

The SA National HIV counselling and testing (HCT) guidelines mandate that provider-initiated HIV counselling and testing (PICT) be offered to all persons attending clinical services in the public and private sectors. However, PICT is time consuming and requires trained HIV counsellors to initiate testing. In busy high-volume EDs, where patients often present in the evenings and weekends, this strategy has been difficult to adopt by many healthcare centres. Therefore HIV testing is not routinely available in many SA EDs.

Given the high burden of disease in SA, the CDC recommended opt-out criteria potentially includes all SA health districts.[4] Opt-out testing is less resource intensive, as it does not require pre-counselling and there is an opportunity to destigmatise the disease. The potential for earlier diagnosis, during ED care, may allow for more accurate diagnosis, especially for infective processes. These aspects will address the concern over lack of autonomy and the potential reduced respect for persons.

From a clinician safety perspective, clinicians benefit by knowing the status of their individual patients. This can reduce stress and inform management should a potential on-duty injury occur, such as a blood splash or needle-stick injury. It may also reduce the need for post-exposure prophylaxis with its attendant side-effects, which is pertinent given the close association of HIV status and other risk-taking behaviours resulting in admission to EDs and trauma units.[33] This safety concern was raised in 1983 (when HIV prevalence was identified as 6% in a US ED) and advocated for the adoption of universal precautions during all patient interventions.[34] This addresses the ethical aspects of social justice.

Given the link between lower socioeconomic status, major trauma and alcohol-related pathology, expanding this policy to include the major trauma patient and the critically ill who are under sedation and on mechanical ventilation will benefit patient care (principle of beneficence), as the clinician will know the status and avoid unnecessary delays in seeking atypical organisms and opportunistic infections (principle of non-maleficence). Providing antiretroviral therapy to critically ill patients who may already be on treatment, but whose status is unknown due to reduced level of consciousness at their time of admission is also important. ED-based testing is also likely to capture high-risk patients, who are unlikely to access primary care where HIV testing is offered.

Although this is a novel approach in SA policies, it makes medical sense given the high rates of HIV/AIDS and trauma and the uprated CD4 levels for initiating HAART. Most research sites excluded sexual assault victims, prisoners and those needing resuscitation, while in SA these are the very persons at risk for a missed early diagnosis of HIV. With the recent announcement that HAART will be available to people with CD4 <500 cells/mm^3 rather than <350 cells/mm^3 and the option of lifelong therapy in all pregnant women,[35] early diagnosis and treatment becomes even more important from a clinical, ethical and public health perspective.

From the ethical perspective a recent robust qualitative study used structured interviews with stratified participants, to poll the views of 25 persons involved in HIV advocacy, care, policy, and research within the USA about the opt-out implementation and its controversial aspects.[36] Opt-out testing improved the process and access to testing, had long-run societal benefits, and allowed individuals earlier linkage to care. Challenges and potential risks or harms included: concerns around informed consent, quality of follow-up after diagnosis, and rushing through the opt-out process to secure testing. From an ethical perspective the respondents all agreed it would enable destigmatising the disease. However, most participants agreed with removing the need for a signed consent form as this removed the need to declare risk-taking behaviour before testing. An identified risk was a loss of 'teachable moments' often identified during pre-counselling under the opt-in system. However the destigmatisation of the disease was of higher significance. They were also hopeful that the ultimate good intent of the recommendations may be developed into a framework for implementation and that helpful dialogues on improving the practicalities of HIV testing would result.

Long-term cost efficacy has been addressed in a systematic review examining the cost saving of surgical access in LMICs. Trauma care was as cost-effective as voluntary counselling and testing, but far more cost-effective than the treatment of HIV/AIDS and TB.[37] While the cost of treating trauma makes sense, it follows to add opt-out HIV testing where that care is provided to further enhance holistic diagnosis and treatment.

However, even with the adoption of an opt-out testing strategy many patients are still likely to reject HIV testing.[23] To maximise test acceptance and subsequent new HIV diagnoses, evidence must be used for decisions about the best way to conduct testing procedures.[38] The SA government is therefore urged to move toward an opt-out testing system in preference to the current opt-in system.

References

1. Rehle T, Johnson L, Hallett T, et al. A comparison of South African national HIV incidence estimates: A critical appraisal of different methods. PLoS One 2015;10(7):e0133255. DOI:10.1371/journal.pone.0133255
2. Girardi E, Sabin CA, Antonella d'Arminio Monforte M. Late diagnosis of HIV infection: Epidemiological features, consequences and strategies to encourage earlier testing. J Acquir Immune Defic Syndr 2007;46(Suppl 1):S3-S8. DOI:10.1097/01.qai.0000286597.57066.2b
3. National AIDS Council. National strategic plan on HIV, STIs and TB 2012-2016. Pretoria: South African National AIDS Council, 2012. http://www.thepresidency.gov.za/MediaLib/Downloads/Home/Publications/SANACCallforNominations/A5summary12-12.pdf (accessed 6 May 2016).
4. Shisana O, Rehle T, Simbayi LC, et al. South African National HIV Prevalence, Incidence and Behaviour Survey, 2012. Cape Town: HSRC Press, 2014:25-26.

5. Hodkinson P, Argent A, Wallis L, et al. Pathways to care for critically ill or injured children: A cohort study from first presentation to healthcare services through to admission to intensive care or death. PloS One 2016;11:e0145473. DOI:10.1371/journal.pone.0145473
6. Rothman RE, Ketlogetswe KS, Dolan T, Wyer PC, Kelen GD. Preventive care in the emergency department: Should emergency departments conduct routine HIV screening? A systematic review. Acad Emerg Med 2003;10(3):278-285.
7. UNAIDS. Joint United Nations Programme on HIV/AIDS (UNAIDS). The Gap Report. Geneva: UNAIDS, 2014.
8. Branson BM, Handsfield HH, Lampe MA, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in healthcare settings. MMWR Recomm Rep 2006;55(RR-14):1-17.
9. World Health Organization. Guidance on provider-initiated HIV testing and counselling in health facilities. Geneva: World Health Organization, 2007. http://www.who.int/hiv/pub/vct/pitc2007/en/ (accessed 6 May 2016).
10. April MA. Rethinking HIV exceptionalism: The ethics of opt-out HIV testing in sub-Saharan Africa. Bull World Health Organ 2010;88(9):703-708. DOI:10.2471/BLT.09.073049
11. Health Systems Trust. Botswana adopts radical approach to HIV. Westville: Health Systems Trust, 2016. http://www.hst.org.za/news/botswana-adopts-radical-approach-hiv (accessed 6 May 2016).
12. Health Systems Trust. South Africa: The HIV testing debate: voluntary or opt-out? Durban: Health Systems Trust, 2016. http://www.hst.org.za/news/south-africa-hiv-testing-debate-voluntary-or-opt-out (accessed 6 May 2016).
13. Waxman MJ, Kimaiyo S, Ongaro N, et al. Initial outcomes of an emergency department rapid HIV testing program in western Kenya. AIDS Patient Care 2007;21(12):981-986. DOI:10.1089/apc.2007.0075
14. Nakanjako D, Kamya M, Daniel K, et al. Acceptance of routine testing for HIV among adult patients at the medical emergency unit at a national referral hospital in Kampala, Uganda. AIDS Behav 2007;11(5):753-758. DOI:10.1007/s10461-006-9180-9
15. Nakanjako D, Kyabayinze DJ, Mayanja-Kizza H, Katabira E, Kamya MR. Eligibility for HIV/AIDS treatment among adults in a medical emergency setting at an urban hospital in Uganda. Afri Health Sci 2007;7(3);124-128. DOI:10.5555/afhs.2007.7.3.124
16. Christensen A, Russ S, Rambaran N, Wright SW. Patient perspectives on opt-out HIV screening in a Guyanese emergency department. Int Health 2012;4(3):185-191. DOI:10.1016/j.inhe.2012.03.001
17. Minz RW, Singh S, Varma S, Mathuria SN, Aggrawal R, Sehgal S. Relevance of opt-out screening for HIV in emergency and pre-surgery patients in a tertiary care center in Northern India: A pilot study. Indian J Pathol Microbiol 2010;53(2):287-289. DOI:10.4103/0377-4929.64334
18. Prekker ME, Gary BM, Patel R, et. al. A comparison of routine, opt-out HIV screening with the expected yield from physician-directed HIV testing in the emergency department. Am J Emerg Med 2015;33(4):506-511. DOI:10.1016/j.ajem.2014.12.057
19. Setse RW, Maxwell CJ. Correlates of HIV testing refusal among emergency department patients in the opt-out testing era. AIDS Behav 2014;18(5):966-971. DOI:10.1007/s10461-013-0654-2
20. White DAE, Sadoun T, Tran T, Alter HJ. Increased acceptance rates of HIV screening using opt-out consent methods in an urban emergency department. J Acquir Immune Defic Syndr 2011;58(3):277-282. DOI:10.1097/QAI.0b013e318231916d
21. Wheatley MA, Copeland B, Shah B, Heilpern K, Del Rio C, Houry D. Efficacy of an emergency department-based HIV screening program in the Deep South. J Urban Health 2011;88(6):1015-1019. DOI:10.1007/s11524-011-9588-z
22. Brown J, Shesser R, Simon G, et al. Routine HIV screening in the emergency department using the new US Centers for Disease Control and Prevention Guidelines: Results from a high-prevalence area. J Acquir Immune Defic Syndr 2007;46(4):395-401.
23. Montoy JCC, Dow WH, Kaplan BC. Patient choice in opt-in, active choice, and opt-out HIV screening: Randomized clinical trial. BMJ 2016;352:h6895. DOI:10.1136/bmj.h6895
24. Chua AC, Leo YS, Cavailler P, et al. Opt-out of voluntary HIV testing: A Singapore hospital's experience. PLoS One 2012;7(4):e34663. DOI:10.1371/journal.pone.0034663
25. White DAE, Scribner AN, Martin ME, Tsai S. A comparison of patient satisfaction with emergency department opt-in and opt-out rapid HIV screening. AIDS Res Treat 2012;2012:904916. DOI:10.1155/2012/904916
26. Batey DS, Hogan VL, Cantor R, et al. Short communication routine HIV testing in the emergency department: Assessment of patient perceptions. Aids Res Hum Retroviruses 2012;28(4):352-356. DOI:10.1089/aid.2011.0074
27. Cowan E, Leider J, Velastegui L, Wexler J, Velloza J, Calderon Y. A qualitative assessment of emergency department patients' knowledge, beliefs, attitudes, and acceptance toward revised HIV testing strategies. Acad Emerg Med 2013;20(3):287-294. DOI:10.1111/acem.12090
28. Czarnogorski M, Brown J, Lee V, et al. The prevalence of undiagnosed HIV infection in those who decline HIV screening in an urban emergency department. AIDS Res Treat 2011;2011:879065. DOI:10.1155/2011/879065
29. Hseih YH, Kelen GD, Beck KJ, et al. Evaluation of hidden HIV infections in an urban ED with a rapid screening program. Am J Emerg Med 2016;34(2):180-184. DOI:10.1016/j.ajem.2015.10.002
30. Haukoos JS, Campbell JD, Conroy AA, et al. Programmatic cost evaluation of nontargeted opt-out rapid HIV screening in the emergency department. PLoS One 2013;8(12):e81565. DOI:10.1371/journal.pone.0081565
31. Menchine M, Zhou M, Lotfipour S, Chakravarthy B. Moving beyond screening: How emergency departments can help extinguish the HIV/AIDS epidemic. West J Emerg Med 2016;17(2):135-138. DOI:10.5811/westjem.2016.1.29100
32. Geren KI, Lovecchio F, Knight J, et al. Identification of acute HIV infection using fourth-generation testing in an opt-out emergency department screening program. Am J Emerg Med 2014;64(5):537-546. DOI:10.1016/j.annemergmed.2014.05.021
33. Hardcastle T, Oosthuizen G, Clarke D, Lutge E. Trauma, a preventable burden of disease in South Africa: Review of the evidence, with a focus on KwaZulu-Natal. In: Padarath A, King J, Mackie E, Casciola J, eds. South African Health Review 2016. Durban: Health Systems Trust, 2016:179-189.
34. Kelen GD, DiGiovanna T, Bisson L, Kalainov D, Sivertson KT, Quinn TC. Human immunodeficiency virus infection in emergency department patients: Epidemiology, clinical presentations, and risk to health care workers: the Johns Hopkins experience. J Am Med Assoc 1989;262(4):516-522.
35. Moorhouse M, Conradie F, Venter F. What is the role of CD4 count in a large public health antiretroviral programme? Afr J HIV Med 2016;17(1):446. DOI:10.4102/sajhivmed.v17i1.446
36. Waxman MJ, Merchant RC, Celada MT, Clark MA. Perspectives on the ethical concerns and justifications of the 2006 Centers for Disease Control and Prevention HIV testing recommendations. BMC Med Ethics 2011;12:24. DOI:10.1186/1472-6939-12-24
37. Grimes CE, Henry JA, Maraka J, Mkandawire NC, Cotton M. Cost-effectiveness of surgery in low- and middle-income countries: A systematic review. World J Surg 2014;38(1):252-263. DOI:10.1007/s00268-013-2243-y
38. Haukoos JS, Rowan SE. Screening for HIV infection. BMJ 2016;532:i1. DOI:10.1136/bmj.i1