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Development of a Valid and Reliable Questionnaire to Identify Ethical Concerns Among Health-Care Professionals Regarding HIV Testing in Different Scenarios

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ABSTRACT

Background

Regarding HIV testing, there are differing opinions and approaches among healthcare professionals due to the ethical dilemmas associated with HIV. Ethical dilemma often encounters in situations such as, a person with risk of HIV infection refuses voluntary HIV testing before marriage, may transmit infection to his/her spouse. In this case, if one principle of ethics, 'autonomy' of the individual is followed then another principle of ethics, 'beneficence' to the spouse is violated and vice-versa. Whatever ethical decision is made, one individual or group is always going to be affected and justice should be done with this individual or group as well. **Objectives:** To develop a valid and reliable questionnaire regarding ethical dilemmas associated with HIV testing in different

scenarios. **Methods**: Item generation, item reduction, item scaling, cognitive interview testing and pretesting were used. The questionnaire was reviewed by experts and was distributed twice to the participants at 15-days intervals to calculate Cronbach's alpha and Intra-class correlation. **Result**: The questionnaire was found to be valid and reliable with overall Cronbach's alpha as 0.802. Intra-class correlation scores for each question in both test and retest were correlated. **Conclusion**: A valid and reliable questionnaire has been developed which can be used to achieve a consensus on controversial ethical issues associated with HIV testing in different scenarios.

Keywords: Ethical Issues, HIV testing, Marriage, Pregnancy, Questionnaires

INTRODUCTION

Globally an average of 36.7 (34.0–39.8) million people were living with HIV (Human Immunodeficiency Virus) and 2.1 (1.8–2.4) million people were newly infected with HIV by the end of 2015 [1]. HIV positive cases were listed as the 33rd cause of morbidity and mortality collectively worldwide in 1990 and became the 5th leading cause by 2010, a 353 % increase [2]. The most important reason for this rapidly increased rate of HIV stems from a lack of awareness from HIV infected individuals about their HIV status. The World Health Organization estimates that less than half of those infected with HIV have been diagnosed [3]. HIV testing is a vital element of HIV prevention and treatment [4]. HIV treatment has been shown to reduce secondary transmission risks by 96% [5]. There is immense need to increase the rate of HIV testing in low-income countries like Nepal where a large number of people are working abroad, away from family for years at a time. However, the social stigma associated with HIV prevents people from seeking HIV testing voluntarily.

The Centers for Disease Control and Prevention's 2006 recommendations for opt-out testing indicate that if the patient has given general consent for health check-up, pre-test counseling and informed consent for the HIV testing are not required; instead, he/she is informed that the testing will be done unless he/she declines the testing [3]. Several states in the United States of America (USA) have implemented mandatory HIV testing policies [6]. The usual opinion of health experts in India is mandatory HIV testing for patients as it is necessary for the safeguard of health experts and other patients [7].

In particular, inmates are at a high risk for HIV infection, such as those with a history of intravenous drug abuse or multiple sex partners. Such individuals should be regularly advised for yearly opt-out testing (where testing is done for all individual unless he/she explicitly declines the test). Enhanced testing has a healthy influence on society because many individuals are likely to decrease their risky behaviors after being diagnosed with HIV [8]. Perceived HIV-associated stigma has been found to be an obstacle to receiving tests for HIV and/or disclosing one's HIV-test result inside correctional facilities [9].

Research articles have shown that people who perceive HIV stigma are less likely to receive HIV test.[10] Sears [11] examined attitudes among health experts in Los Angeles between 2003 and 2006 and reported that 56 % of skilled nursing staff, 26 % of cosmetic surgeons, and 47 % of obstetricians refused to provide any service to patients living with HIV regardless of disease state. This attitude of medical professionals discourages an individual from HIV testing and disclosing his/her HIV status. United States National HIV/AIDS Strategy (2010) aims to provide high quality life-extending services to HIV patients irrespective of age, sex, race, social and economic status [12]. Thus, in 2010

overall percentage of persons in USA who reported having ever been tested for HIV increased from 37 % in 2000 to 45 % [13].

In the U.S., a national survey [14] of 864 physicians and 1339 members of general public revealed that 63 percent of Americans believe that mandatory HIV testing would improve the overall health of the US population. Similar survey in developing countries like Nepal would assist the policy makers in knowing the views of professionals and public regarding the types of choice for HIV testing (i.e. **Voluntary**-choice without any condition; **Conditional**-choice but under a condition and the condition is mentioned within the adjacent bracket; **Mandatory**-No choice). Together, they can assess the most appropriate and most acceptable policies on HIV testing. Once HIV testing is done, its disclosure, particularly in HIV positive case, bears an ethical dilemmas such as a poor pregnant woman who was tested HIV positive during her antenatal visit requested doctor not to disclose the result to her spouse or any other relative because of her fear to lose emotional, economical and other supports. If her request is accepted, one principle of ethics i.e. autonomy is followed but another principle of ethics i.e. beneficence is violated by putting her unborn child and her relatives at risk of HIV infection and vice-versa. Whatever ethical decision is made, one individual or group is always going to be affected and justice should be seen to be done with this individual or group as well. Achieving an agreement on such controversial ethical issues is not an easy task. The World Medical Association ensures that its ethical policy statements reflect a consensus by requiring a 75% vote in favor of any new or revised policy at its annual Assembly. Thus, in the process of achieving consensus for ethical policy regarding HIV testing, a valid and reliable questionnaire is required. This study is done with an objective to develop a valid and reliable questionnaire regarding ethical dilemmas associated with HIV testing in different scenarios.

MATERIALS AND METHODS

We performed item generation, reduction, scaling, cognitive interview testing, and pretesting as described below in order to develop the questionnaire. The study was conducted among subjects above 18 years who gave written informed consents. To test the validity and reliability, the questionnaire was distributed among 120 students of 4th year MBBS (Bachelor of Medicine & Bachelor of Surgery), out of which 89 participants returned the completed questionnaire forms. Ethical approval was taken from the Institutional Review Committee of B. P. Koirala Institute of Health Sciences, Dharan, Nepal.

Item Generation: Literatures related to laws regulating HIV testing in different countries were reviewed. The points supporting HIV testing were used as a template for developing the questionnaire. Colleagues were also consulted to include unpublished important items. After this, colleagues with expertise in the field of health related laws were interviewed. Finally, patients and their relatives were informally interviewed about the difficulties they faced or are facing due to HIV testing.

Item Reduction: An expert panel consisting of the chief questionnaire developer, five forensic experts, a cardio-thoracic surgeon, an endodontic surgeon and a statistician reviewed the items generated. They decided that four domains— HIV testing in association with Marriage (HTAM), HIV testing in association with Pregnancy (HTAP), HIV testing in association with Health-sector (HTAHS), and HIV testing in association with Duty toward third party (HTADTP) —were necessary with 5, 14, 10 and 12 questions respectively. Items were reduced based on Cronbach's alpha and Kappa statistics (Table III)

Item Scaling: Each answer was scored in decreasing order-maximum for most expected answer (i.e. answers supporting HIV testing) and minimum for the least expected answer.

Face/content validity: Six forensic experts and two transplant surgeons were given the questionnaire for reviewing its contents and comment on overall understandings, specifically on any question they would add, delete, or modify. One suggestion was to add a question regarding any law related with HIV/AIDS. All the experts validated the questionnaire with suggestions for minor corrections in some questions.

Cognitive interview testing: Think aloud type of interviewing was conducted where fifteen 3rd year MBBS students were given the questionnaire and were asked to discuss among themselves. The discussion was focused on particular questions including "How easy or difficult did you find this questionnaire to answer? Were you able to find your first answer to the question from the response options shown? and so on". Participants found difficulty in understanding the meaning of some terms for which, it was decided to clarify them by giving an explanation of each term in an adjacent bracket. In relation to the questions with option as "Yes", "No" and "Can't say", initially there were only "Yes" and "No" options. The option "can't say" was added after this discussion. Finally, participants were asked to rephrase each question of the questionnaire in their own words. The meaning of each rephrased questions were compared and no difference between the actual or paraphrased questions was found.

RESULTS

Pretesting: Pretesting conducted among fifteen 3rd year MBBS students with interaction on each question had shown the questionnaire to be valid and reliable for testing and retesting. For obtaining informed opinions, participants were provided with some of facts regarding HIV/AIDS as shown in Table I below.

Table I

Facts on HIV/AIDS that supports its early testing, early diagnosis and early disclosure

- Advances in treatment have transformed an HIV diagnosis from a near death sentence to a manageable chronic disease [15].
- Like other chronic diseases, it requires continuous family and society support which is possible only with disclosure of HIV infection status [16,17].
- Patients who had not disclosed, or who disclosed only to family, were more likely to present with a CD4 count <200 cell/mm3 [18].
- Delaying diagnosis increases mortality: Individuals diagnosed late with HIV are ten times more likely to die in the first year after diagnosis than those diagnosed earlier [19].
- Diagnosing HIV benefits others: Diagnosing HIV enables modification of sexual behavior and lowering viral load with medication further reduces transmission [20].
- Diagnosis facilitates partner notification and contact tracing so that others can themselves benefit from early diagnosis and treatment.
- A study has shown the prevalence of unprotected anal and vaginal sexual intercourse (UAV) with any partner was an average of 53% (95% confidence interval [CI]: 45%–60%) lower in HIV positive persons aware of their status relative to HIV positive persons unaware of their status [6].

Reliability: Testing was conducted among 89 (out of 120) 4th year MBBS students, without any interaction, had shown the questionnaires to be reliable. The overall Cronbach's alpha was 0.802 and this value didn't increase after deleting any items. Domain-wise overall Cronbach's alpha was 0.787 which didn't increase after deleting any domains. The corrected interdomain-total correlation were 0.649, 0.728, 0.591 and 0.575 for HIV testing in association with the domains; HTAM, HTAP, HTAHS, and HTADTP respectively. (Table: II)

Table 1 - II: Test Reliability

Domain	No. of Questions in each Domain	Cronbach's Alpha if Domain Deleted	Corrected Domain- Total Correlation
HTAM*	5	0.766	0.649
HTAP**	14	0.702	0.728
HTAHS***	10	0.756	0.591
HTADTP****	12	0.772	0.575

*HIV testing in association with Marriage

**HIV testing in association with Pregnancy

***HIV testing in association with Health-sector

****HIV testing in association with Duty toward third party

Test-retest reliability and inter-raters reliability: Test-retest was conducted among the same 89 randomly selected 5th year MBBS students at 15 day intervals and intra-class correlation for each question was calculated. Scores for each question in the initial test and retest were correlated as shown in Table - III. The Kappa score for each question was also calculated by 89 participants to determine inter-raters reliability as shown in Table - III.

Table 2 - III: Test-Retest Reliability & Kappa Scores

Question Number	Test- Retest: Intraclass Correlation*	Kappa Scores*	Question Number	Test- Retest: Intraclass Correlation*	Kappa Scores*
1	0.696	0.470	22	0.594	0.419
2	0.676	0.467	23	0.776	0.631
3	0.547	0.438	24	0.573	0.477
4	0.741	0.604	25	0.620	0.518
5	0.700	0.475	26	0.697	0.512
6	1	0.491	27	0.640	0.460
7	0.555	0.537	28	0.574	0.400
8	0.695	0.531	29	0.820	0.632
9	0.667	0.476	30	0.701	0.584
10	0.698	0.491	31	0.692	0.527
11	0.583	0.478	32	0.563	0.662
12	0.563	0.851	33	0.550	0.401
13	0.522	0.503	34	0.557	0.414
14	0.746	0.499	35	0.676	0.508
15	0.692	0.526	36	0.921	0.851
16	0.606	0.539	37	0.806	0.670
17	0.791	0.652	38	0.902	0.820
18	1	0.663	39	0.839	0.720
19	0.887	0.794	40	0.816	0.624
20	0.684	0.456	41	0.514	0.470
21	0.633	0.453			

*Correlation is significant at the 0.01 level.

Factor analysis was carried out for total scores obtained in each domain with the help of principal component analysis using direct oblimin rotation. Only one factor, 'HIV testing' was present in this study which was supported by examination of eigenvalue and scree plot. An examination of the Kaiser-Meyer-Olkin measure of sampling adequacy indicated that the sample was factorable (Kaiser-Meyer-Olkin = 0.708), and Bartlett's test of sphericity was significant, $\chi 2 = 65.846$, $p < .001$

DISCUSSION

This cross-sectional study was conducted to generate a questionnaire regarding ethical dilemma associated with HIV testing in different scenarios. The questionnaire has been found to be valid and reliable. The reliability testing, done without any interaction, has shown that the questionnaire is not complicated, can be self-administered, can avoid some potential for observer bias and needs no special training to administer the test. All the participants who participated in test also participated in retest done after 15 days and intra class correlation between test and retest for each question was moderate to strong (positively correlated). Kappa scores have shown moderate to almost perfect inter-rater agreement. Kaiser-Meyer-Olkin measure above 0.6 and significant Bartlett's test of sphericity indicated sample size is adequate for factorable and examination of eigenvalue and scree plot has supported our single factor measurement i.e. HIV testing. Each question is preceded by some information which would act as campaign for encouraging HIV testing.

HIV is in need of a proper regulating system to encourage testing and discourage the stigma and discrimination associated with it. In any country, HIV infection is mainly guided by the people who are at high risk such as female sex workers, intra-venous drug abusers, homosexuality, and so on [21-25]. A study done in New York City jail has shown that if HIV testing is not expanded or targeted to high-risk inmates, many infections will go unreported or undiagnosed [26]. At the same time, the provision of testing only to high risk groups increases the feeling of discrimination which further increases both external and internal stigma among them. Thus, HIV testing should be made a routine test for every individual. Routine screening for HIV infection is recommended for patients in all healthcare settings to reduce the number of persons unaware of their infection and to detect HIV infection early [27, 28]. In this research, the questionnaire was developed in order to take the views of professionals and public regarding whether the testing be done in different scenarios (marriage, pregnancy, delivery, lactation, and health sectors). For the response supporting the HIV testing, further questions were asked regarding the types of choice for HIV testing. The results of the questionnaire will guide health professionals in proper ethical decision-making. The questionnaire was also developed to tackle the ethical issues related with disclosure of the result because the disclosure, particularly of positive case, is too difficult. Regarding disclosure, Ghana has a policy that requires all newly diagnosed individuals to get counseling on disclosure and partner notification. The individuals are encouraged and permitted to disclose either by themselves at home or in the presence of the counselor. The policy does not permit counselors to reveal an individual's HIV status to partner(s) without his/her consent [29].

While the world-wide incidence of HIV seem to have steadied in current years, HIV among married or sharing heterosexual pairs has remained high in many parts of Africa [30-32]. In situations where conflicting partners decide to have a child, they can be supported to attain a pregnancy with reduced risk to the uninfected partner if positive HIV status has already been disclosed [33]. The infected partner will be able to adhere to timetables given for medical attention and antiretroviral therapy with support from the partner as shown in studies in Uganda, Zambia and China [34-36]. Of approximately 4000 HIV-positive pregnant women delivering annually in Ukraine, the majority (around 60 %) in a recent study [37] have been diagnosed with HIV via antenatal screening during that pregnancy. In Ukraine, fifty percent of HIV-positive population in a 2011 study stated having experienced stigma or discrimination from other people as a result of their HIV status [38] and stigma related obstacles to disclosure may be especially noticeable for pregnant women, who may

fear that disclosure may put them under the threat of rejection, discrimination and loss of a partner's or spouse's support [39-42].

Convergent validity could not be performed as similar studies could not be found with which correlation test could be done. Discriminant validity was also not assessed because of the simplicity of the questionnaires whose responses were not affected by presence or absence of participant's knowledge regarding HIV testing.

CONCLUSION

A valid and reliable questionnaire has been developed which can be used to achieve local, national and international consensus on controversial ethical issues associated with HIV testing. This questionnaire is recommended for researchers from different countries of the world so that the professionals and public opinions thus gathered will be of relevance to their respective nations and may provide a guide for policy-makers regarding HIV testing.

COMPETING INTERESTS

The authors declare no conflict of interests.

SUPPLEMENTAL MATERIAL

The questionnaire **"**Ethical Concerns among Health-Care Professionals regarding HIV Testing in Different Scenarios" can be accessed at publisher's website.

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