
Analysis of quality assurance programmes for HIV screening in blood transfusion centres in Delhi

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The safety of blood transfusion has attained tremendous importance because of the problems posed by acquired immunodeficiency syndrome (AIDS) and other transfusion-transmissible diseases. While performing screening tests for human immunodeficiency virus (HIV) antibodies in donated blood is indispensable, it is also essential to introduce an effective quality assurance programme covering inspection of specimens, review of record-keeping, maintenance of equipment, and verification of results. We carried out an analysis of such quality assurance programmes during routine annual inspection of 11 blood transfusion centres in Delhi, India. The following parameters were studied: standardization of sample collection and handling; adherence to the recommended technical procedure; use of standard operating procedure; proper use of test reagents; laboratory record-keeping; proper handling of HIV-positive blood units; recording and communication of results; observation of safety guidelines; equipment quality control; and training of staff. A pre-tested closed-type questionnaire with a weighted scoring system was used for evaluation. Performance for each parameter was graded as follows: 76–100%, excellent; 51–75%, good; 26–50%, fair; and <25%, poor. Centres were categorized according to the total score obtained for all parameters. Overall performance >50% was considered satisfactory. Of the 11 centres, none was excellent overall, five were considered satisfactory, and six were unsatisfactory.

Introduction

The modes of transmission of human immunodeficiency virus (HIV) are now well understood. Although HIV transmission through blood transfusion accounts for only a small proportion of new infections, its efficiency is >90% (1). However, as the risk of HIV transmission through blood transfusion depends on the prevalence of infected individuals in the donor population, the possibility of such transmission can be minimized by selecting donors at low risk for HIV infection and by screening the donated blood for HIV antibodies. It is also important to ensure the appropriate use of blood and blood products in order to avoid unnecessary transfusions and exposure of recipients to the risk of transfusion-transmitted disease.

The choice of a suitable screening test depends on the objectives of the screening, the sensitivity and

specificity of available tests, and the prevalence of HIV infection in the donor population. Certain strategies have been recommended by WHO (2,7). For the purpose of transfusion safety, for all prevalences, it is recommended that all blood donations be tested with one highly sensitive assay, e.g. enzyme-linked immunosorbent assay (ELISA). A reactive serum sample is considered HIV-positive and a non-reactive one, HIV-negative. All positive units (on the basis of one test) are discarded.

As for other laboratory procedures, it is essential to introduce an effective quality assurance programme covering inspection of specimens, maintenance of equipment, the choice of assay, record-keeping, and verification of results. Such a quality assurance programme is an essential part of achieving the transfusion of a safe unit of blood. Quality assurance in HIV testing also minimizes the wastage of blood units based on false-positive results.

Materials and methods

Quality assurance programmes for HIV screening were analysed during routine annual inspection of 11 blood transfusion centres in Delhi, India. The 10 parameters studied are described in Fig. 1–10. A pre-tested closed-type questionnaire with a weighted scoring system was used for the evaluation. Weights

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assigned to elements of the various parameters are detailed in Fig. 1–10. For each parameter, all the centres were graded according to score, as follows: 76–100%, excellent; 51–75%, good; 26–50%, fair; and <25%, poor. Overall performance >50% was considered satisfactory.

Results

Standardized sample collection and handling (Fig. 1). Sample collection and handling were good in three centres and fair in eight centres. None scored excellent and one, poor.

Adherence to recommended technical procedure (Fig. 2). Adherence to recommended technical procedure was good in three centres and fair in five. Two centres scored excellent and one, poor. In particular, preservation and use of reconstituted reagents was a cause for concern.

Use of standard operating procedure (Fig. 3). Seven centres did not use any standard operating procedure; one laboratory's use was fair, while three centres were excellent.

Proper use of reagents (Fig. 4). Use of reagents was good in two centres and fair in three. One centre scored excellent and five, poor. Eight centres did not pay adequate attention to checking the sensitivity and specificity of the reagents employed.

Fig. 1. Blood transfusion centres' scores for standardized sample collection and handling for HIV-screening tests (points). I: accurate labelling and identification (2); II: sample clear without turbidity (2); III: sera obtained from fully clotted blood (1); IV: sample non-haemolysed and non-lipaemic (2); V: sample without added preservative (1); VI: sample frozen and thawed < twice (1); VII: storage ≤ -20°C (1); VIII: transport in insulated containers (2).

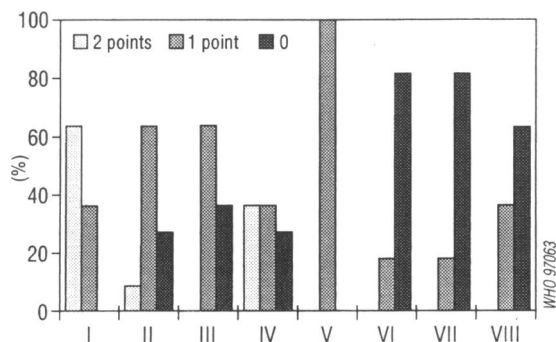


Fig. 2. Blood transfusion centres' scores for adherence to recommended technical procedure for HIV-screening tests (points). I: validation of procedure for each kit (2); II: careful pipetting of samples and reagents (1); III: adherence to kit manufacturer's instructions (2); IV: duplicate testing of initially positive samples (1); V: testing of positive and negative kit controls (1); VI: testing of positive and negative internal controls (1); VII: correct preservation and use of reconstituted reagents (1); VIII: each test run valid (1); IX: external quality control system (2).

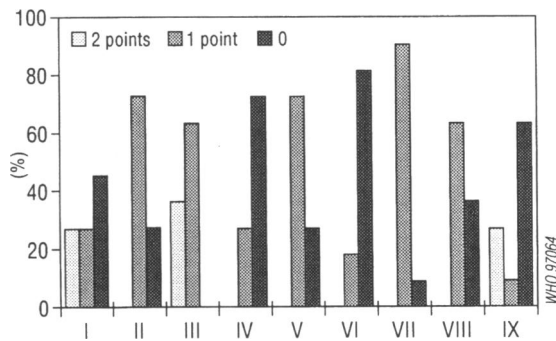
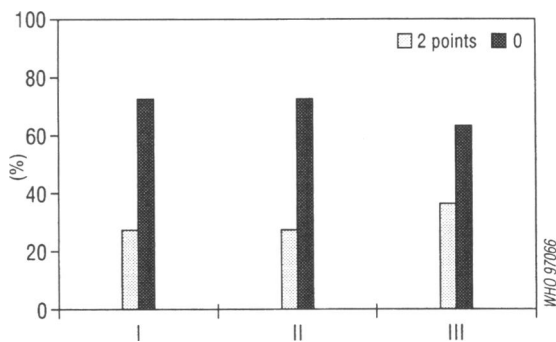


Fig. 3. Blood transfusion centres' scores for use of standard operating procedure for HIV-screening tests (points). I: provision of standard operating procedures (2); II: regular review of standard operating procedures (2); III: written procedures available for related activities (2).



Laboratory record-keeping (Fig. 5). Record-keeping was good in three centres and fair in three others. Two centres scored excellent and three, poor. Only two centres employed a computerized record-keeping system. Laboratory worksheets did not uniformly mention the type, the batch and the lot number, and the expiry date of the test kit used.

Fig. 4. Blood transfusion centres' scores for proper use of reagents for HIV-screening tests (points). I: used according to manufacturer's instructions (1); II: quality checks for each batch included: (a) sensitivity (1); (b) specificity (1); (c) expiry date (1); III: appropriate storage (1); IV: adequate stock maintenance (1); V: adequate temperature control for transport of kits and reagents (2); VI: adequate availability of consumables and disposables (2).

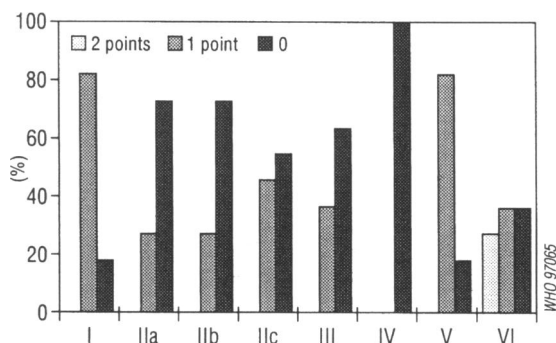
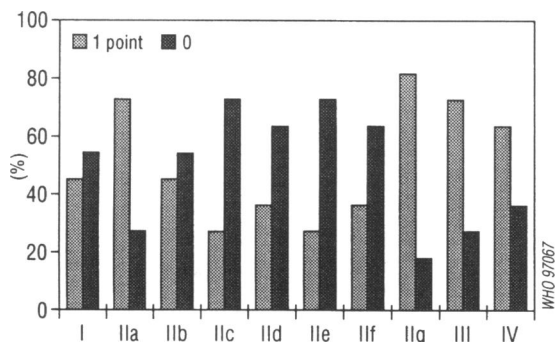
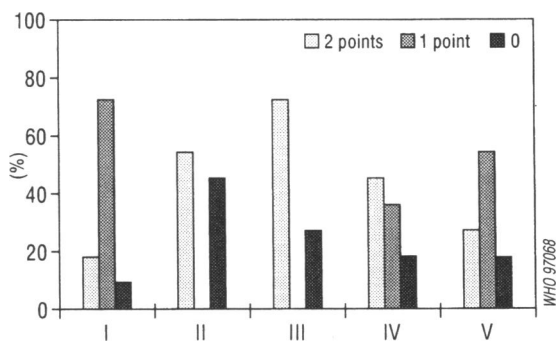


Fig. 5. Blood transfusion centres' scores for laboratory record-keeping for HIV-screening tests (points). I: records satisfactory (1); II: laboratory worksheet includes: (a) plan of investigation (1); (b) clear instructions for sample dispensing (1); (c) type of kit used (1); (d) batch and lot number (1); (e) expiry date (1); (f) incubation time and temperature (1); (g) date of test (1); III: results of positive and negative controls recorded (1); IV: original test results preserved (1).



Proper handling of HIV-positive blood units (Fig. 6). Handling and disposal of HIV-positive blood units were good in five centres and fair in two centres; three centres scored excellent and one, poor. Such units were not always labelled clearly in nine centres. Five centres did not dispose of HIV-positive blood units immediately. Similarly, eight centres did

Fig. 6. Blood transfusion centres' scores for proper handling of HIV-positive blood units (points). I: clear identification and labelling (2); II: immediate removal and destruction (2); III: maintenance of disposal record (2); IV: adequate disinfection of waste (2); V: appropriate disposal of blood and waste (2).



not practise the most satisfactory disposal method for infected waste and blood, i.e. incineration.

Recording and communication of test results (Fig. 7). Recording and communication of test results were good in three centres and fair in four; two centres scored excellent and two, poor. In six centres, assay results were not always recorded, or if they were, they were not always recorded correctly.

Observation of safety guidelines (Fig. 8). Observation of safety guidelines was good in three centres and fair in seven centres. One centre scored excellent and none, poor. Two centres were still practising mouth pipetting. Seven centres had no restriction on eating, drinking, smoking, and applying cosmetics in the laboratory. Staff in two centres did not regularly wear gloves while working in the laboratory. Measures to reduce aerosol formation were not followed in eight centres. In nine centres, staff performed paperwork in the work area. In eight centres, working benches were not regularly disinfected. The use of laboratory coats and the protection of cuts and wounds were not routine in three and two centres, respectively. Hand washing was the only safety procedure regularly and universally followed in all centres.

Equipment quality control (Fig. 9). Equipment quality control was good in three centres and fair in six centres. None scored excellent and two, poor. In only three centres did equipment in the laboratory conform to manufacturer's specifications. No centre had annual service contracts for all important

Fig. 7. Blood transfusion centres' scores for recording and communication of HIV-screening test results (points). I: accurate recording of results (2); II: ELISA results preserved (2); III: information recorded included: (a) donation No. (1); (b) initial results (1); (c) final results (1); (d) final action regarding donation (1); IV: prompt communication of results (2).

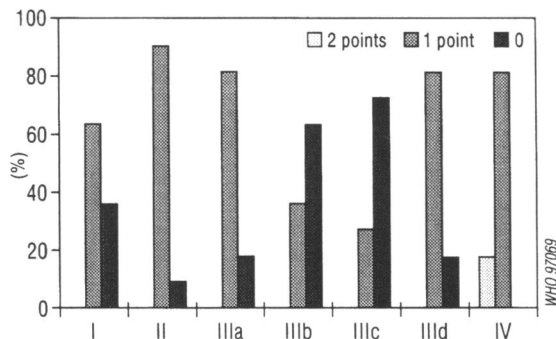
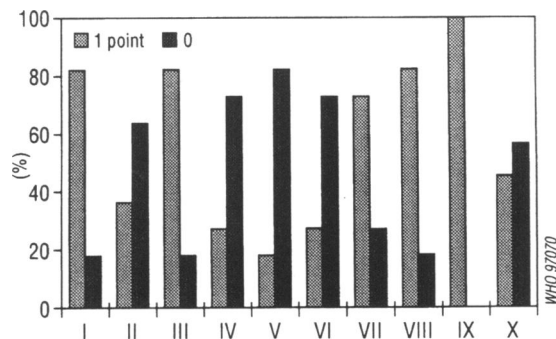


Fig. 8. Blood transfusion centres' scores for observation of safety guidelines for HIV-screening tests (points). I: automated pipetting used (1); II: eating/drinking/smoking prohibited (1); III: safety gloves required (1); IV: aerosol reduction employed (1); V: separate area used for paperwork (1); VI: regular disinfection of workbenches performed (1); VII: laboratory coats routinely used (1); VIII: cuts and wounds protected (1); IX: hand washing performed on exit (1); X: access limited (1).



laboratory equipment. However, nine centres did have an assured power supply for most temperature-controlled equipment.

Training of staff (Fig. 10). Staff training was good in two centres and fair in five centres. One centre scored excellent and three, poor. In five centres, only

Fig. 9. Blood transfusion centres' scores for equipment quality control for HIV-screening tests (points). I: equipment conforms to manufacturer's specifications (2); II: annual service contract for equipment maintenance (2); III: record of service visits maintained (2); IV: assured power supply for equipment (2); V: periodic validation of equipment function (2).

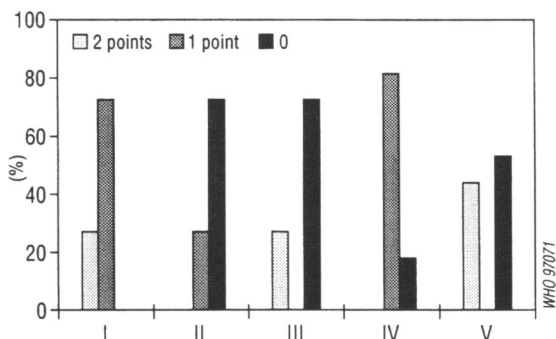
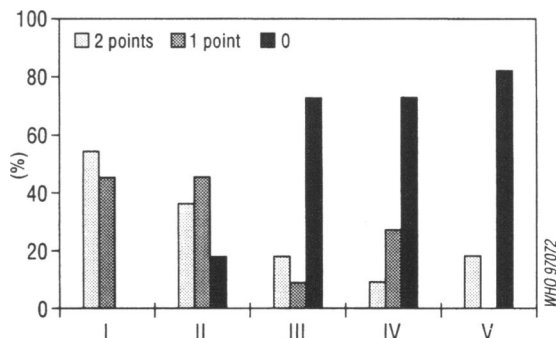


Fig. 10. Blood transfusion centres' scores for training of staff for HIV-screening tests (points). I: staff sufficiently trained (2); II: level of knowledge of staff adequate (2); III: periodic validation of staff proficiency (2); IV: regular in-service training (2); V: availability of teaching/training material (2).



some staff members received adequate training for working in an HIV laboratory. In nine centres, staff proficiency was not periodically validated. Provision of regular in-service training was lacking in eight centres. Appropriate training material was not available for staff in nine centres.

Of the 11 centres evaluated, none had a total score for all the parameters examined qualifying as either excellent or poor; five centres were considered satisfactory (good), and six were unsatisfactory (fair) (Table 1).

Table 1: Blood transfusion centres' scores for studied parameters for quality assurance of HIV-screening tests

Centre	Parameter score: ^a										Total ^c
	1(12) ^b	2(12)	3(6)	4(10)	5(10)	6(10)	7(10)	8(10)	9(10)	10(10)	
1	8	10	0	5	7	8	6	5	5	3	57
2	8	7	6	4	5	6	8	7	7	6	64
3	9	11	6	7	4	8	7	8	6	8	74
4	6	7	6	5	4	6	8	5	5	3	55
5	6	8	2	8	8	7	4	7	6	6	62
6	5	4	0	2	8	1	6	6	2	3	37
7	6	6	0	6	6	4	4	3	5	2	42
8	6	2	0	1	6	8	4	3	2	3	35
9	3	4	0	2	2	5	2	4	3	2	27
10	4	5	0	2	2	6	2	4	5	2	32
11	5	5	0	1	1	7	4	3	4	3	33

^a Parameters are coded as follows: 1: standardized sample collection and handling; 2: adherence to recommended technical procedure; 3: use of standard operating procedure; 4: proper use of reagents; 5: laboratory record-keeping; 6: proper handling of HIV-positive blood units; 7: recording and communication of test results; 8: observation of safety guidelines; 9: equipment quality control; 10: training of staff.

^b Figures in parentheses are total possible points for the parameter.

^c Out of 100 possible.

Discussion

Although many reports have emphasized the need for external quality control systems in HIV screening (3–5), the level of quality assurance implementation by blood transfusion centres in India has not been previously reported. The findings presented here are derived from spot checks of working conditions in the HIV laboratories in the centres evaluated and from information provided by staff. Therefore, some evaluation bias cannot be ruled out. Since the investigators are employed by one of the centres, inspection of this centre was carried out by an independent person using the same questionnaire.

We found significant lapses in a majority of blood transfusion centres in Delhi, India, with respect to the quality control parameters evaluated. Serious breaches were detected in a few centres regarding standard operating procedure, proper use of reagents, and observation of safety guidelines.

Standardization of sample collection and handling should be improved in eight centres. Emphasis should also be given to proper use of reagents and adherence to recommended technical procedures. The labelling and the removal and destruction of HIV-positive blood units need to be improved in nine and five centres, respectively, and the availability and review of standard operating procedures need to be improved in eight centres. Record-keeping, in particular the design and organization of laboratory worksheets, needs improvement in eight centres, and additional stress should be given to observation of safety guidelines in seven. Equipment quality control and staff training should be improved in eight of the centres. It is therefore evident that

implementation of effective quality assurance programmes for HIV testing in blood transfusion centres in Delhi, India is essential.

Résumé

Analyse des programmes d'assurance de la qualité pour le dépistage du VIH dans les centres de transfusion sanguine

La sécurité des transfusions de sang est devenue d'une importance primordiale du fait des problèmes posés par le SIDA (syndrome d'immunodéficience acquise) et les autres maladies pouvant être transmises par voie transfusionnelle. S'il est indispensable de procéder au dépistage des anticorps anti-VIH (virus de l'immunodéficience humaine) dans les dons de sang, il est également essentiel d'adopter des programmes d'assurance de la qualité portant sur l'inspection des échantillons, l'examen des registres, l'entretien du matériel et la vérification des résultats. Nous avons effectué une analyse de ces programmes lors de l'inspection annuelle de routine de 11 centres de transfusion sanguine à Delhi, Inde. Les paramètres suivants ont été étudiés: standardisation du prélèvement et de la manipulation des échantillons, respect du protocole technique recommandé, utilisation de modes opératoires normalisés, utilisation correcte des réactifs, tenue des registres du laboratoire, manipulation correcte des unités de sang positives pour le VIH, enregistrement et notification des résultats, respect des directives de sécurité, contrôle de la qualité du

matériel, et formation du personnel. Un questionnaire fermé, préalablement testé, a été utilisé pour l'évaluation, avec un système de notation pondérée. Chaque paramètre a été noté comme suit: 76–100%, excellent; 51–75%, bon; 26–50%, assez bon; <25%, médiocre. Les centres ont été classés en fonction de la note totale obtenue pour l'ensemble des paramètres. Une qualité globale >50% était jugée satisfaisante. Sur les 11 centres, aucun n'a été classé comme excellent, 5 ont été classés comme satisfaisants et 6 comme non satisfaisants.

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