SHORT REPORT

Benefits of a rapid HIV test for evaluation of the source patient after occupational exposure of healthcare workers


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Summary Rapid human immunodeficiency virus (HIV) testing for the management of occupational exposure of healthcare workers significantly decreased the number of anti-retroviral post-exposure prophylaxis regimens started whilst awaiting HIV test results. The study confirmed an equivalent performance of the rapid test in comparison with HIV enzyme immunoassay, and suggests it is cost-effective. In addition, two other potential benefits emerged: reducing the number of source patients who remain untested and increasing the number of occupational exposures reported.

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Introduction

Current guidelines for the management of occupational exposure to blood recommend that healthcare workers (HCWs) report all exposures and the source patient be tested for, at least, hepatitis B (HBV), and C viruses (HCV) and human immunodeficiency virus (HIV) in order to plan appropriate follow-up, including anti-retroviral post-exposure prophylaxis (PEP),1-3 which should be initiated as soon as possible after exposure. However, as the HIV status of the source is usually not known at exposure, a number of HCWs start PEP awaiting the source patient’s test results, and interrupt it when the source is found to be HIV-negative.4-7

Rapid HIV tests provide results in a short time, have sensitivity and specificity comparable with the conventional enzyme immunoassay (EIA), and can be considered as a screening method to increase the proportion of HCWs to whom the source
patients' HIV test results are known within a few hours after an exposure.\(^8\)

We analysed the effects of introducing a rapid HIV test on exposure management in two Italian public Hospitals: St Anna University of Ferrara (hospital A) and the University Hospital of Perugia (hospital B).

### Methods

In Italy, national guidelines from the Ministry of Health recommend a combination PEP consisting of two nucleoside reverse transcriptase inhibitors and adding a protease inhibitor for higher risk exposure.\(^2,3\)

Capillus HIV-1/HIV-2 (Cambridge Biotech Corp., Worcester, MA, USA), is the only rapid HIV assay licensed in Italy. The Capillus test yields a quantitative result to detect antibodies against HIV 1 and HIV 2 in serum and plasma in approximately 45 min. The reaction of latex agglutination is monitored by a digital reading, which gives either a positive, negative, or indeterminate result, with a sensitivity and a specificity approaching 100%.\(^9,10\)

In both hospitals the following data were collected: number of occupational exposures reported, source patients tested for HIV, HCWs consenting to PEP, and the number of PEP that were stopped after the source tested HIV negative. The interval between the exposure and the source patient's HIV test result was also calculated. In both hospitals, laboratory working hours did not include public holidays or nightshifts, when the EIA HIV test could not be performed.

In hospital A, a first attempt was made in 1998 by establishing a preferential route of HIV EIA testing in cases of occupational exposure, which reduced the average exposure-to-test result time from 36 h in 1997 down to 22.5 h. In 1999, Capillus was introduced into routine use to be performed on an urgent basis, around the clock, seven days a week, including holidays. Specimens that tested HIV-1 positive with the Capillus assay were further tested by EIA, and if positive, by Western blot; specimens testing negative were reported as HIV-1/HIV-2 seronegative. The laboratory at hospital A used the EIA IMx HIV-1/HIV-2 Plus in the pre-intervention period, and the AxSYM HIV1/HIV2 Plus (both manufactured by ABBOTT, Wiesbaden-Germany) in the rapid test period.

In hospital B, a pilot study was started in September 2001, adding Capillus to the conventional EIA (HIV Combi EIA-COBAS CORE, Roche Diagnostics GmbH, Mannheim, Germany), in order to evaluate the feasibility of a programme aimed at reducing the exposure-to-test result time, which was an average of 36 h at that time. HCW occupational exposures reported up to August 2002 were compared with those of the 1995–1999 period, when anti-HIV tests were performed only with conventional EIA. No data are available for the period January 2000 to September 2001. No other changes were made to the hospital protocol for the management of occupational exposure during the study periods.

### Results

Table I lists the features of occupational exposures reported in the two hospitals. In both hospitals the introduction of rapid HIV testing significantly reduced the number of HCW who were given unnecessary PEP. In the rapid-test period a significantly lower number of source patients remained untested \((P < 0.001)\).

In hospital A, in all 90 cases of PEP provided in 1997–1998, the initial drug regimen consisted of zidovudine plus lamivudine; indinavir was added in the six cases when the source tested HIV-positive. In the 84 cases where the source tested HIV-negative, the HCW stopped PEP after being exposed to 388 doses of zidovudine plus lamivudine. During the rapid-test period, three patients tested HIV positive with the Capillus test, and started a PEP regimen consisting of zidovudine, lamivudine and indinavir or nelfinavir. All positive results were confirmed by Western blot.

According to the hospital pharmacy data, the Capillus and HIV EIA assay cost around €7 and €4 per test, respectively. Thus, the total cost using the rapid HIV test was €4088 for 584 patients; had the enzyme-linked immunoassay (ELISA) test been used instead of the rapid test, the total cost would have been €2336: an incremental cost of €1752. Of note, the cost of unnecessary PEP in the pre-intervention period was around €1800 (388 doses of zidovudine plus lamivudine at a cost of €5 per dose).

In hospital B, PEP regimens varied from zidovudine monotherapy in 1995–1996, zidovudine plus lamivudine in 1997, and zidovudine, lamivudine and indinavir or nelfinavir in 1998–1999 and 2001–2002. A 15-fold increase in the number of reported occupational exposure was observed during the rapid-test period, despite a similar number of beds. The EIA test showed a 100% concordance with the results obtained by the rapid test. All specimens that tested HIV positive with the Capillus and the EIA were confirmed by Western blot.
Discussion

In both hospitals, rapid HIV testing was a useful tool for evaluation of the source patient after an occupational exposure of HCWs. The most important advantage of the introduction of rapid test was a reduction of HCWs who were given unnecessary PEP. Findings from Hospital B, and the absence of false-positive results in both hospitals, show the good performance of the rapid test when compared with the conventional EIA. Moreover, although a formal cost analysis was not performed, data from hospital A suggests that the rapid test method can be cost-effective, because its higher cost in comparison with EIA can be counterbalanced by cost savings by not administering anti-retroviral therapy. These findings were not unexpected. Indeed, several other studies have published similar results on test performance, cost-effectiveness, and implementation of PEP provision in healthcare, as well as in other settings. Our study suggests two other potential benefits from the introduction of a rapid test in the management of occupational exposures in the healthcare setting: a reduced number of source patients who remain untested, as observed in both the hospitals, and an increased reporting of occupational exposures, as observed in hospital B.

Lack of compliance with exposure reporting protocols is a well-known phenomenon; patients supposedly negative, and complex reporting procedures are indicated as main reasons for not reporting. Uncertainty about the HIV status of a source patient involved in a case of occupational exposure has a clear impact on the anxiety of HCWs who need to comply with clinical, and serological follow-up, as well as with infection transmission precautions. The relatively high prevalence of HIV infection among tested source patients seems to support the finding that HCWs are more prone to report those exposures that are likely to be high risk.

However, rapid availability of a source patient’s positive HIV test result seems to have reduced the physicians’ uncertainty of which PEP regimen should be provided, with the immediate inclusion of a protease inhibitor in the PEP. We can only speculate that the easier management of HIV testing, due to rapid-test availability, accounted for these findings. Because of the retrospective design of the study we cannot exclude other reasons that were not investigated.

For hospital B, a potential limitation lies in the comparison of non-consecutive time periods. However, this fact should not have altered the validity of the observed findings; indeed, the only change made in the hospital management of occupational exposures in the years 1995-2002 was the introduction of this rapid test. For hospital A, the introduction of the rapid test was associated with longer laboratory work hours, a fact that could account for most of the observed findings.

It must be conceded that an EIA test per se only requires approximately 2-6 h for the result, and that the availability of immediate EIA HIV testing of the source may limit unnecessary PEP. However, the time between the exposure, specimen collection, and EIA test result strongly depend upon the hospital and laboratory organization and on workload. In fact, in many hospitals due to laboratory constraints, the EIA may not be performed daily or more than once a day, outside working hours, and during holidays, so test results may not be available for three to five days. Rapid HIV tests require minimal equipment and reagents. 'Capillus’ does not require highly skilled staff, can be performed on site a short time after specimen collection, and is very easy to interpret. Our study suggests that rapid HIV tests can contribute to the best management of occupational exposures in the healthcare setting.

<table>
<thead>
<tr>
<th>Year</th>
<th>Hospital A</th>
<th>Hospital B</th>
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<tbody>
<tr>
<td>Beds</td>
<td>900</td>
<td>710</td>
</tr>
<tr>
<td>HIV antibody assay</td>
<td>EIA</td>
<td>Rapid test</td>
</tr>
<tr>
<td>Number of exposures reported, Mean (beds/month)</td>
<td>567 (0.3)</td>
<td>628 (0.3)</td>
</tr>
<tr>
<td>Number of source patients tested for HIV</td>
<td>395</td>
<td>584</td>
</tr>
<tr>
<td>Number of healthcare workers starting PEP</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Number of healthcare workers stopping PEP after the source tested negative</td>
<td>84</td>
<td>0</td>
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EIA, enzyme immunoassay; PEP, HIV post-exposure prophylaxis.

a P < 0.001 by Chi-square in both hospitals.


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References