Stimulating reporting of adverse drug reactions by using a fee

John Feely, Siobhan Moriarty, Patricia O’Connor

Despite its limitations, spontaneous (yellow card) reporting of adverse drug reactions is the most effective surveillance system of drugs in clinical practice. Nevertheless, fewer than 10% of reactions are usually reported.1 Because of the use of multiple and potent drugs and because of the failure to report reactions to occur more commonly in hospital than the reported 0·05%.1 To enhance the level of reporting we performed two studies: firstly a pharmacist collated reports, and, secondly, we offered a fee for each yellow card received.


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Stevens-Johnson syndrome. An independent assessment of a random 25% sample confirmed the reports in over 90% of cases. A survey of the 40 reporting doctors identified "forgot/too busy" (4), unavailability of forms (18), and uncertainty about reporting system (6) as main constraints in reporting. The fee was an incentive for 32. In the six weeks after withdrawal of the fee only 30 reports were received by the registrar.

Comment
Enhanced rates of reporting drug reactions will improve overall drug assessment, reduce bias, and speed earlier detection of serious toxicity with new drugs. Over the past six years our 800 bed hospital (15,000 admissions yearly) has generated almost 0.2% yellow cards per patient. Offering a fee increased the rate of reporting by almost 50-fold, to 9.7%, whereas the pharmacist's survey detected a rate (5.4%) comparable to that in previous studies. Nevertheless, it identified a potential source of additional reports—nurses.

In the fee study we were unable to distinguish the value of reporting to an individual colleague, which we believe is important, and the contribution of the fee, but the number of reports fell substantially after withdrawal of the fee. Two constraints—availability of yellow cards and lack of information on what to report—should be remediable. To counter the main constraint, "lack of time/forgetfulness," we can try only to ensure that reporting of reactions becomes an integral part of patient care.

Reporting fees are used in collecting other medical information such as notifiable diseases. We regard the use of a fee to stimulate reporting as an additional tool in drug assessment. Not only did use of the fee greatly enhance the number of reports, producing almost the equivalent to the previous six years' reports within six weeks; it also revealed many serious reactions, including those associated with newer treatments. In the normal course of events these reactions go unreported. We also introduced recently qualified doctors to the reporting system: 48% of the target group (in our case junior doctors) reported reactions over six weeks compared with a figure of 16% over 10 years for the current system. Further evaluation of the use of a reporting fee is warranted.

We thank the staff of St James's Hospital and the National Drugs Advisory Board for their cooperation.


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Women's knowledge of their HIV antibody state: its effect on their decision whether to continue the pregnancy

Frank D Johnstone, Ray P Brettle, Linda R MacCallum, Jacqueline Mok, John F Peutherer, Sheila Burns

Little is known about the attitudes of women infected with HIV towards pregnancy and whether they decide to continue a pregnancy or terminate it. It is often assumed that a high proportion of women who find that they are infected will terminate their pregnancy because of the risk to the baby, the possible risks to themselves, and their potentially limited life span. The main risk factors for HIV infection among women in Edinburgh are intravenous use of drugs and being the sexual partner of an infected drug user.1 We studied the decisions made about pregnancy in all women with these risk factors.

Patients, methods, and results
A detailed community based record has been created for all pregnancies in women with the above risk factors whose HIV antibody state is known.1,2 Great care is taken to ensure both completeness and confidentiality of this record. We excluded pregnancies that spontaneously aborted, those confirmed before January 1986, and those in women who did not know before 22 weeks or termination whether they were positive for HIV antibodies. We thus studied 163 pregnancies. Standard counselling was provided by several doctors and counsellors.

Induced abortion was common in both the women with and without HIV antibodies (table). Although a higher proportion of the women with HIV antibodies had induced abortions, the difference was not significant (χ² = 1.22, p > 0.20). Forty four women knew that they were positive for HIV antibodies when they became pregnant, and 21 of these had the pregnancy terminated. HIV infection was the main or only reason for termination in at least nine pregnancies: two of the women had AIDS and two had other illness related to HIV infection. Twenty five women were found to have HIV antibodies during pregnancy and knew the result before 22 weeks. Ten of these women had termination of pregnancy, but nine had previously requested abortion on other grounds and had been tested at that consultation. All 15 women who were found to have HIV antibodies when they attended the antenatal clinic continued their pregnancy. The 38 women who continued their pregnancy despite knowing that they had HIV antibodies in early pregnancy did so because they were currently in good health, desired to have one child, were against abortion, and knew women whose children were well and apparently not infected.

Outcome of pregnancy in women who were intravenous drug users or sexual partners of drug users positive for HIV antibodies

<table>
<thead>
<tr>
<th>Total No of pregnancies</th>
<th>% No (%) of induced abortions</th>
<th>95% Confidence interval (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women positive for HIV antibodies</td>
<td>Tested before pregnancy</td>
<td>Tested during first pregnancy</td>
</tr>
<tr>
<td>Tested before pregnancy</td>
<td>69</td>
<td>31 (45)</td>
</tr>
<tr>
<td>Tested during first pregnancy</td>
<td>44</td>
<td>21 (48)</td>
</tr>
<tr>
<td>All women</td>
<td>94</td>
<td>33 (35)</td>
</tr>
</tbody>
</table>

* Spontaneous abortions and women who did not know their antibody state before 22 weeks of pregnancy were excluded.

Comment
The combination of pregnancy and HIV infection can necessitate difficult decisions. The women we studied had a high rate of induced abortion, whether or not they were infected with HIV; the rate was nearly three times that in the city's overall population. Finding during pregnancy that they had HIV anti-