In India we have a large drug consuming population. There is a plethora of counterfeit and substandard drugs [1], drugs belonging to alternative systems of medicine like ayurveda, unani, siddha, homeopathy and drugs which have been banned/withdrawn in other countries [2]. Because of these factors, it is all the more important that a system of adverse drug reaction (ADR) reporting is established. In addition, without a proper ADR database, it is difficult to withdraw harmful drugs from the market.

The enormity of the problem of ADR reporting and poor post marketing surveillance by pharmaceutical companies in India is well documented [3]. India rates below 1% in terms of ADR reporting against the world rate of 5% [4]. This clearly shows that the concept is still in its infancy here. To overcome this, the Ministry of Health & Family Welfare has initiated the National Pharmacovigilance Programme (NPP) which is co-ordinated by the Central Drugs Standard Control Organisation (CDSCO) in New Delhi. Under this programme 24 peripheral, five regional and two zonal Pharmacovigilance Centres are asked to work cohesively to improve ADR reporting in India [5].

A major proportion of India’s population prefers government hospitals when seeking health care facilities. This means that a good ADR database can be generated from these hospitals. The most difficult task initially is to foster a culture of reporting among clinicians especially junior doctors who have the most contact with patients. Reasons for the low level of ADR reporting include lack of awareness, training, and most importantly, time. An additional factor is that the government has not made it mandatory for health care providers to report ADRs unlike some countries such as Spain and Sweden. Hence, there is definitely a need for spontaneous ADR reporting from these physicians [6].

The only way to inculcate the habit of ADR reporting among doctors, besides education programmes is to provide them with an easy and quick method of reporting. We carried out an extensive education programme for all clinicians and interns on the importance of ADR reporting and provided them with a simple method, by which to report ADRs (Figure 1).

Figure 1
Adverse Drug Reaction (ADR) notification drop box with ADR notification forms (right) and ADR alert cards (left)

Safely locked ‘ADR notification drop boxes’ [7] (with the key purpose printed on them) were installed systematically in all the wards and selected outpatient departments (OPDs) in the hospital. Together with the boxes ‘ADR notification forms’ were kept. The form was designed in such a way that the ‘notifier’ (doctor, intern, medical student or nurse) finds it very easy to report an ADR. The moment any health care provider suspects an ADR, a duly filled notification form should be dropped in the ‘ADR notification drop box’. We collected and analyzed the notified ADRs at regular intervals. The drug manufacturer’s name was tracked down as per the brand details provided by the ‘notifier’. In the case of hospital supply, the same was tracked down with the assistance from hospital pharmacy. On getting the required details, a red coloured CDSCO reporting form, provided by the pharmacovigilance centre, was completed. ADR reporting increased from 14 to 32 reports in the course of a 3 month period after the education programme and the introduction of the ‘ADR notification drop boxes’. This method has gained popularity among the doctors (Table 1). Monthly reports
collected from the whole hospital were then forwarded to the pharmacovigilance centre. Confidentiality was maintained at all levels.

To ensure patient safety, each patient with an ADR was provided with an ‘ADR alert card’ at the time of discharge, which was kept by the patient and presented to other health care providers when needed in the future.

To get sustained results from this strategy for reporting ADRs, there should be strong collaboration between the Department of Pharmacology and other clinical departments. ADR monitoring should be a compulsory part of training for postgraduate students in the Department of Pharmacology, as a part of their M.D. curriculum. Lectures should be taken at the undergraduate level on the importance of pharmacovigilance and ADR reporting. Students could be given an exercise such as to report three ADRs in their term which they can do during their ward postings. Interns can be taught about ADR reporting during their Internship Orientation Programme, so that they too can assist the resident doctors working in various clinical departments. The Department of Pharmacology should provide pharmacovigilance awareness programmes to all the nurses and other allied health staff working in the hospital. Assistance should be provided by the CDSCO to sponsor ADR boxes, notification forms and ADR alert cards under the National Pharmacovigilance Programme (NPP).

This strategy if adopted by all the government hospitals as well as government medical colleges could be a useful stepping stone in generating a genuine ADR database for our population. All marketed drugs could be monitored simultaneously. Another way could be a computer based online reporting system which is utilized by many developed countries but may be a challenge for public hospitals in developing countries like India.

### Table 1
Number of ADRs reported to the Peripheral Pharmacovigilance Centre (Goa), India, in the 3 months after installing the ‘ADR notification drop boxes’ in the hospital

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of ADRs reported</th>
</tr>
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<tbody>
<tr>
<td>January 2008</td>
<td>14</td>
</tr>
<tr>
<td>February 2008</td>
<td>23</td>
</tr>
<tr>
<td>March 2008</td>
<td>32</td>
</tr>
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### REFERENCES