

# Reporting of Adverse Drug Reactions by Consumers : Rationale and Potential

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## ABSTRACT

*To assess the feasibility of involving consumers in reporting and monitoring adverse drugs reactions (ADR) in India, a household survey was carried out in three states of India, namely Andhra Pradesh, Maharashtra and Uttar Pradesh using a pre-tested questionnaire. Responses were obtained from a total of 566 households in three states together. Also elicited were the opinions of other stakeholders such as (a) hospitals and nursing homes, (b) private medical practitioners, (c) chemists and (d) pharmacovigilance centres with regard to involving household in the reporting of ADRs. A huge 93 per cent of the households are willing to report ADRs. Other stakeholders are also in favour of involving consumers in the reporting of ADRs and believe that it is a good idea. It is concluded that in cases where an ADR is likely to occur at, an ADR form may be given to the consumer at the time of prescribing by doctors or of dispensing by chemists. A prepaid system of providing an inland letter/envelop is a feasible option for encouraging consumers to report the ADRs experienced by them.*

## INTRODUCTION

National pharmacovigilance programmes monitor Adverse Drug Reactions (ADRs) and help to improve the safety of medicines prescribed. Under-reporting is a major concern in national pharmacovigilance programmes, especially those dependent on spontaneous reporting<sup>1,2</sup>.

Patients consume medicines at home. Advertising promotes the tendency to self-medicate, which might lead to inappropriate use of medicines and ADRs. In principle, patients/consumers have a vested interest in reporting ADRs. Hence, consumers/patients can be an important source of such reporting<sup>3</sup>.

Patients in the United States were the first to get an opportunity to report ADRs directly to the Food and Drug Administration (FDA) in the 1960s. In April 2003, Dutch patients began to report possible ADRs to LAREB, a foundation separate from the country's national drug regulatory authority. Denmark allowed patients or relatives to report ADRs from June 2003. In Italy, patients have been able to download a special form to report ADRs to the AIFA (Italian Drug Regulatory Agency) since 2004. A consumer organization, Test-Achats/Test-Aankoop (TA), was established in Belgium in 2006 to accept reports from patients and transfer them to the Federal Agency for Medicines and Health Products (FAMHP). Medicines and Health Related Products Regulatory Agency (MHRA) in the UK made substantial efforts in February 2008 to raise awareness so as to increase the number of reports from patients. The website of Swedish Medical Products Agency (MPA) added an interactive section to enable patients and consumers to report ADRs in June 2008. Norwegian Medicines Agency started accepting electronic reports directly from patients since March 2010. The consumer-focused reporting service in Australia-Adverse Medicines Events Line (AMEL), a telephone hotline was begun in October 2003<sup>4</sup>. KILEN, run by a consumer group in Sweden, has been receiving reports from patients since 1978 and also provides feedback to those submitting reports<sup>5</sup>.

## OBJECTIVE

India launched the National Pharmacovigilance Programme (NPVP) in April 2004 based on spontaneous reporting. The Government of India was keen to explore different options for improving

the reporting and monitoring of ADRs under NPVP<sup>6</sup>. The objective of the present study was to assess the feasibility of involving patients/consumers in reporting and monitoring of ADRs in India. Besides consumers (households), a number of other stakeholders were also considered for assessing the options for improving the reporting and monitoring of ADRs under NPVP.

## **METHODS**

Three states in India, namely Andhra Pradesh, Maharashtra and Uttar Pradesh were selected for the study. In each state, three districts were selected at random. A total of 566 households were interviewed between February and June 2006. About 42% of the households are from urban areas, and 58% are from rural areas. About 73% of the respondents are male. About 21% per cent had studied up to 12 the class and about 29% studied beyond. About 22% are daily wage earners, 24% are in service and 15% are in business. The monthly income of about 30% is below Rs. 2000, and about 56% are in the income group of Rs 2,000-10,000.

## **RESULTS**

### **Household Perspective**

$\frac{3}{4}$  of households had at least one member taking medicines during the past three-month period from the date of survey. Awareness about NPVP among the households in India is less than 2%. About 50% of the respondents rated the problem of ADRs as very important and 45 per cent as important on a five point Likert type scale. The vast majority (93%) mentioned that they are willing to report ADRs. About 84% of the households wanted the ADR forms to be available at hospitals/nursing homes and 6% preferred chemists. While 7% mentioned that they require help in filling up the forms, 19% stated that they could do it on their own (the non-response rate was very high for this question.) About 57% of the respondents preferred hospitals for sending in the filled-up forms, while 22% preferred doctors and 4% preferred chemists. The most preferred mode for sending in the filled-up form is by post (45%), while about 38% preferred delivering it by hand. About 43% suggested the need for creating mass awareness through advertisement in different media and about 21% expressed the need for educating the patient. About 10% mentioned that the ADR forms should be in the local language.

### **Opinion of Other Stakeholders**

Majority of the other stakeholders contacted in this study are also in favour of involving patients/consumers in the reporting of ADRs. About 66% out of 148 hospitals and nursing homes have opined that it is a good idea to give the ADR form to the patients in OPD or to the inpatients at the time of discharge for select drugs and ask them to send in the filled-up form in case they experience ADRs. About three fourths of the 172 Private Medical Practitioners (PMPs) contacted for the study are in favour of giving ADR forms to patients coming to them (for a select list of drugs) and asking them to send in the filled-up ADR forms to them or to a designated centre. About 54% out of 189 chemists, felt that it is good idea to give an ADR form to the patients at the time of purchase of selective drugs.

Even the pharmacovigilance centres participated in the study were favourably inclined towards the involvement of consumers/patients in ADR reporting. Eleven out of the sixteen peripheral centres and two out of the three regional centres, who responded, supported involvement of consumers in ADR reporting.

All the stakeholders emphasized the need for generating awareness using mass media and other appropriate means, among common citizens as well as different stakeholders, before the consumers can be involved in the reporting of ADRs.

## DISCUSSION

ADR reports have several advantages. They have value as a quantitative indicator of quality and safety<sup>7</sup>. Patient reports contain data on personal and social consequences<sup>8</sup>. Medawar<sup>9</sup> found individual patient reports much richer in their descriptions of behavioural phenomena and feelings compared to the Yellow Card reports submitted by professionals in the UK. He concluded that though individually such reports may be deficient or exaggerated and sometimes wrong, collectively they reflect good common sense. O'Brien<sup>10</sup> found the information on ADRs to be analytical.

Jarernsripornkul<sup>11</sup>, observed that patient perceptions of potential ADRs provides useful information but GPs do not report all the symptoms told to them by patients. Hence, he recommended that they should be an integral part of any pain management strategy<sup>12</sup>. A study of users of two popular non-steroidal anti-inflammatory drugs (NSAIDs) in Australia<sup>13</sup> revealed reactions that often evade detection during pre-marketing clinical trials. Reviewing published literature, Blenkinsopp<sup>14</sup> observed that reports by patients identified possible new ADRs that had not previously been reported by health professionals.

Campbell and Howie<sup>15</sup> reported that the patients, who were prescribed a black triangle drug (a new drug put under intensive surveillance by MHRA in UK) increased from 10 per 1000 to 23 per 1000 in two months. A study of 650 adults with self-reported ADRs to statins in the US revealed that it is mostly patients who initiate the discussion with their physicians and concluded that targeting patients is likely to boost the yield of ADR reporting systems<sup>16</sup>.

Disproportionality analysis of two data sets of data on ADRs, namely (a) only from health care providers and (b) from health care providers as well as consumers, by Glaxo Smith Kline in the US, found that in 52.2% of events, the signal was identified earlier when consumer reports were included in the data<sup>17</sup>. A Dutch study<sup>18</sup> mentions that patients reported new suspected reactions to paroxetine (an antidepressant) on an average, 273 days before doctors reported the same reaction.

Partnering with in-patients is a promising strategy to prevent adverse drug events. In a prospective study involving 107 inpatients of a teaching hospital in a Boston, 29% of the nurses indicated that at least one medication error was prevented when a patient or family member identified a problem<sup>19</sup>.

However, Lampela<sup>20</sup> found a great disparity between the adverse effects identified by the physician and those reported by a group of elderly patients in Finland. It may be because the elderly people tend to neglect adverse drug effects and may consider them to be an unavoidable part of normal ageing.

The 2004 European law regarding medicinal products (726/2004/EC Article 22) states that "Patients shall be encouraged to communicate any adverse reaction to health-care professionals." Aspden<sup>21</sup> presented various scenarios (a) clinicians provide appropriate instructions and encouragement to patients for reporting adverse side effects, (b) reporting systems with multiple options capture reports of medication errors from patients and families, and (c) resources to address complications from prescriptions are available around the clock. A Working Group on Patient in the UK proposed methods such as use of posters in outlets that stock patient Yellow Cards, use of advertising, feedback for people and promotion through the media, for reporting of ADRs. It is also necessary that sufficient resources are made available for this purpose<sup>22</sup>.

## CONCLUSIONS

All over the world there is an increasing trend of involving consumers in the process of health care. Consumer reporting has several advantages like qualitative details; increase in ADRs reported, newer

ADRs being reported, early detection of ADRs and also as a strategy to prevent medication errors. Moreover allowing patients to report demonstrates a necessary attitudinal change towards showing greater respect to those experiencing illness and taking medicines<sup>6</sup>. None of the countries with patient reporting systems has reported poor quality of patient reports to be an issue<sup>23</sup>.

Recent reports from developing countries also are in favour of consumer reporting of ADRs. Fernandopulle<sup>24</sup> has suggested that an independent consumer reporting system complements the present health professional-based system in Sri Lanka. Gunawardena<sup>25</sup> used pharmacovigilance based on consumer feedback in Sri Lanka. Ahmed<sup>26</sup> emphasized the need for involving consumers in the existing pharmacovigilance programme in Malaysia and Palaian<sup>27</sup> suggested a novel approach.

The present study suggests a favourable picture on the involvement of consumers in reporting ADRs. Though India is experiencing an IT revolution, many respondents preferred to use the hard copy of the ADR form for filling-up and sending in. This is not surprising as the level of penetration of computers and the Internet at the household level is very low. Hardly 3% of the sample households contacted in the study have access to computer and 2% to the Internet. Hence, a prepaid postage system, inland letter/envelop, may be developed to encourage consumers to report the ADRs directly to NPVP or to the nearby hospital or chemist from which they regularly obtain health care services. Prepaid postage forms are being used for ADR reporting by consumers in Canada, UK, USA and Australia. There should be a wide-spread media campaign on the importance and means of reporting ADRs by consumers, supported by patient education. van Hunsel<sup>28</sup> reported that media attention affects drug use and ADR reporting by patients in Netherlands.

However, there is a need for piloting before consumer reporting can be made an integral part of the National Pharmacovigilance Programme in India. LAREB in Netherlands piloted it for one year between April 2003 and March 2004 before it decided to continue the reporting station for patients<sup>29</sup>. It will be useful to understand: (a) What motivates a person to take the trouble to report an ADR? (b) How to create an enabling environment to motivate them? (c) How to make the ADR reporting forms easily accessible to people? (d) What kind of support systems are to be put in place for effective involvement of consumers in ADR reporting and monitoring?

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