Practicality of direct Reporting Of ADRs by Patients

Evaluation using survey of KAPs of patients towards ADRs & ADR reporting

Mala Kharkar
Suresh Bowalekar

Presentation – An outline

- Introduction- Adverse Drug Reaction (ADR)
- ADR Reporting – Indian Scenario
- Underreporting of ADRs – Significant issue
- Background
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Introduction - Adverse Drug Reaction (ADR)

Adverse Drug Reaction (ADR)

- Unwanted or unexpected effect of a drug / medicine.
- Known as “Side Effect of Drug / Medicine” among laymen

Almost all approved drugs have

- potential to cause ADRs during normal therapeutic use

ADRs at times

- resulted in morbidity and mortality all over the world

Hence, attempt is made to produce medicines which are

1. Safe have minimum risk of hazards like ADRs &
2. Efficacious – beneficial to patients in terms of efficacy

Introduction - Adverse Drug Reaction (ADR)

During the drug developmental process, studies experiments are conducted to assess safety (detect ADRs) & efficacy, however, in the experimental set up, there are certain limitations like,

1. Limited number of patients,
2. Restrictions on patients- inclusion / exclusion criteria
3. Limited exposure to medicine - duration of treatment,&
4. dosage schedule

Introduction - Adverse Drug Reaction (ADR)

- ADRs / side effects are generally rare so get manifested after
  - "long-term use in clinical practice" as against "experimental / Clinical Trial set up"
- Marketing approvals given are based on the results of studies
  - with limited number of patients
  - for relatively short period (trial period) of drug usage
- Marketing approvals are given (in India DCGI), subject to collection of data on ADRs by conducting Post Marketing Surveillance (PMS) Studies in normal clinical practice within post approval period of 2 years

Introduction - Adverse Drug Reaction (ADR)

- Drug Regulatory Authorities of all countries : responsible for approving only safe and efficacious medicines
- Hence, Regulatory authorities request following groups
  - Drug Manufacturing companies- which produce drugs
  - Healthcare Professionals – who treat patients
  - Researchers and scientist – involved in drug development

to report any ADR/(s) observed by them / reported by patients to the Drug Regulatory Authorities directly or via ADR Monitoring centres

ADR Reporting -Indian Scenario

- 1986 : Started Pharmacovigilance (PV) concept in India which grew with good pace.
- 1997 : India joined WHO program for International Drug monitoring managed by Uppsala monitoring centre, Sweden
- 2005 -2009 : Establishment of National PV program - WHO sponsored and World bank funded with advisory committee based in Central Drugs Standard Control Organization (CDSCO), New Delhi.
- From 2010, PV Program of India (PvPI) is in action.

Underreporting – Significant Issue

- However, healthcare professionals fail to report / avoid reporting of some ADRs because of following reasons
  - ADRs well known
  - ADRs too trivial
  - Causality uncertain
  - Lack of time due to primary role of patient care

Hence, with minor variations

"under-reporting of ADRs" : a major issue all over the globe

Thus, all over the globe
Under reporting of ADRs is a significant issue

Background

In order to find solution to the issue of underreporting of ADRs,

- In some Developing countries : Patient / patient's relative is allowed to report ADRs directly to concerned authorities.
- Hence, it was decided to assess practicality of using patients in India to report ADRs directly to ADR concerned authorities
- By conducting a survey to examine the level of knowledge, attitude and practice (KAP) of patients in India about ADRs & ADR reporting.

Objectives

1. To assess Knowledge, Attitude, Practices/perceptions (KAPs) of patients towards ADR and ADR reporting
2. Based on the findings of data generated in the survey, to decide about
   a) the current level of KAP of patients towards ADRs and ADR reporting
   b) the training needs of patients to improve their current level of understanding about and ADR reporting
   c) the practicality of using patients for reporting ADRs directly to concerned authorities and thus
   d) provide solution to current issue of underreporting of ADRs

Research Methods - Conduct of survey

- The **questionnaire** used was
  - prepared in English
  - **pre-tested & validated**
  - translated into national language
  - approved by an independent Ethics Committee.

- The survey was conducted by researchers and **trained field-force** of pharmaceutical companies

Research Methods - Sample Size

- Six patients were randomly selected from 1000 medical practitioners' clinics@.
- Received the response of 5040 patients out of 6000 selected.

@ = Medical Practitioners participated in previous published study[1]

[1] = Kharkar M, Bowalekar S. (2012) Knowledge, attitude and perceptions/practices (KAP) of medical practitioners in India towards adverse drug reaction (ADR) reporting. Perspect Clin Res 3:90-4

Results

Demographic Profile of Patients

Total Number of Patients :	
Randomly selected	6000
Approached / Contacted	5735 (95.6%)
Responded	5040 (84.0%)
Age (Years) :	
Mean	30.61
Standard Deviation (S.D.)	7.54
Range (Min – Max)	18 - 86
Sex :	
Males	3388 (67.2%)
Females	1652 (32.8%)

Results (Contd.)

Academic background of Patients

Educational Qualification	No. of Patients	(%)
No Schooling	357	7.08
SSC	609	12.08
HSC	**1287**	**25.54**
Diploma Holders	**832**	**16.51**
Graduates	**1757**	**34.86**
Post Graduates	**187**	**3.71**
No response	11	0.22
Total	**5040**	**100.00**

Highlights

55% patients – diploma holders, graduates and above
80% patients above HSC (HSC 25%)

Results (Contd.)

Occupation of responding patients

Occupation	**Number of Patients**	**(%)**
Student	454	9.01
Unemployed	68	1.35
Home care taker	522	10.36
Service	**3529**	**70.02**
Business	424	8.41
Not responded	43	0.85
Total	**5040**	**100.00**

Highlights 70% patients – services as occupation

Results (Contd.)

Distribution of Patients by Annual income

Annual Income	No. of Patients	Percentage (%)
Less than 50,000	526	10.44
50,000 – 1,00,000	**1568**	**31.11**
1,00,000 – 2,00,000	**1915**	**37.99**
2,00,000 – 5,00,000	**248**	**4.92**
More than 5,00,000	11	0.22
Not responded	772	15.32
Total	**5040**	**100.00**

Highlights 69% patients – had ANNUAL income between Rs 50K & 200K

Results (Contd.)

Awareness/ Attitude Parameters

No.	Parameters	Yes	No	(%) Yes
1	Necessity of family doctor	794	4246	15.8
2	**Aware of the term side effect**	**2194**	**2846@**	**43.5**
3	**Experienced side effect**	**2776**	**2264@**	**55.1**
4	Check the information of medicine before consuming	1782	3258@	35.3
5	Group the medicine as safe or unsafe based on information	736*	4304@	14.6
6	**Aware of ADR centers**	**1051**	**3989@**	**20.9**
7	**Reported ADR to ADR centers**	**890**	**4150@**	**17.7**

@ - Patients not responding – clubbed with patients responded as “No”.
* - The response “yes” includes response “sometimes” also.

Highlights

55% patients – experienced ADRs
43% patients – aware of term side effects
21% patients – had idea about ADR centres
17% patients – reported ADRs to ADR centres

Results (Contd.)

Source of advice / suggestions for choice of medicine

No	Source	No. of Patients	(%)
1	**Any doctor**	**4323**	**85.78**
2	Doctor suggested by friend / relative / family doctor	178	3.54
3	Nearby Public Hospital / Health Care Professionals / Centers	61	1.22
4	From a friend / relative	7	0.14
5	Try traditional medicines / home remedies	16	0.32
6	Get medicine from multiple sources	345	6.81
7	No response	110	2.19
Total :		**5040**	**100.00**

Highlights 86% patients – Not particular about fixed doctor, ready to consult any doctor

Results (Contd.)

Distribution of patients taking action on

No. of patients who took action on ADR / Side effect	Action taken	No. of patients	(%)
171	**Informed doctor who gave medicine but he told not to worry**	**145**	**84.8**
	Informed doctor who gave medicine he told to stop the medicine	6	3.5
	Informed friend / relative who told not to worry, it happens with the medicine	0	0
	Not taken any action	1	0.5
	Not responded	19	0.1

Highlights 85% patients – were told not to worry about ADRs by doctor
Is there a chance that these ADRs were not reported by doctor?

Results (Contd.)

Sources of knowledge for patients about term ADR

No.	Knew about ADRs from	No. of patients	(%)
1	**Doctor**	**2724**	**54.05**
2	Friends / Relatives	19	0.38
3	Pharmacist / Chemist	20	0.39
4	Internet	6	0.12
5	Other	2	0.04
6	Knew about ADRs from multiple source described above	30	0.60
8	**Not responded / no**	**2239**	**44.42**
Total		**5040**	**100.00**

Highlights

54% patients – came to know about term ADR from the doctor
44% patients – knew nothing about ADRs (No response)
02% patients – knew about tem ADR from other sources

Results (Contd.)

Type of information collected on medicine before its consumption

No.	Information (tried to gather)	No. of patients	(%)
1	**Efficacy or effectiveness**	**1435**	**28.47**
2	Indication for which medicine is used.	59	1.17
3	**Possible side effects**	**33**	**0.66**
4	**Serious side effects / Serious ADRs**	**10**	**0.19**
5	**Warnings**	**10**	**0.19**
6	Direction and usage	27	0.54
7	Interactions with other drug	3	0.06
8	Multiple information	187	3.71
9	No response / Don't know	3276	65.01
Total		**5040**	**100.00**

Highlights

29% patients – Collected information on efficacy before using
About 1% patients – collected information on ADRs / Side Effects

Results (Contd.)

Distribution of Patients by action taken after experiencing ADR

No.	Action taken	No. of patients	(%)
1	**Informed Doctor**	**2809**	**55.73**
2	**Informed Pharmacist / Chemist**	**17**	**0.34**
3	Tried traditional medicine	10	0.20
4	Stopped taking medicine	5	0.09
5	**Not responded / No action /**	**2199**	**43.64**
Total		5040	100.00

Highlights

56% patients – informed doctor / pharmacist / chemist
44% patients – not responded / no action

After knowing about ADRs during survey

Results (Contd.)

Action planned by patients to deal with ADRs in future

No.	Action taken	No. of pts.	(%)
1	**Informed Doctor**	**4376**	**86.82**
2	**Informed Pharmacist / Chemist**	**50**	**0.99**
3	Treat with traditional medicine	30	0.60
4	Take advice of friends/ relatives	21	0.42
5	Stop taking medicine	240	4.76
6	Multiple actions	190	3.71
7	Not responded / No	133	1.15
Total		**5040**	**100.00**

Highlights

88% patients – changed and decided to inform doctor / pharmacist / chemist about ADR

Results (Contd.)

Source of information used to collect on medicine

No.	Source	No. of patients	(%)
1	**Doctor who gave the medicine**	**1430**	**28.37**
2	**Other doctor**	**89**	**1.76**
3	Friends / Relatives	46	0.92
4	Chemist shop / Pharmacist	46	0.92
5	Internet	21	0.41
6	Multiple sources	79	1.56
7	**Don't know / Not responded**	**3329**	**66.06**
Total		**5040**	**100.00**

Highlights

28% patients – Collected information about medicine from Doctor
66% patients – Not responded / didn't know about such information

After knowing about ADRs during survey

Results (Contd.)

Future plans of patients for collection of information on medicine

Sr. No.	Future planned source	No. of patients	(%)
1	**Doctor who gave the medicine**	**1514**	**30.03**
2	Other doctors	44	0.88
3	Friends / Relatives	5	0.10
4	Chemist shop / Pharmacist	4	0.08
5	Internet	12	0.24
6	Multiple sources	198	3.93
7	**Don't know / No Response**	**3263**	**64.74**
Total		**5040**	**100.00**

Highlights

30% patients – decided to ask doctor for information of med.
65% patients – still unaware of planned source of information.

Results (Contd.)

Patients' view on authorities responsible for unsafe medicines

No.	Authority	No. of patients	(%)
1	**Company**	**1712**	**33.97**
2	**Drug Authority**	**287**	**5.69**
3	**Doctor who prescribes medicine**	**1738**	**34.48**
4	**All of above**	**607**	**12.04**
5	Combination of authorities	152	3.02
6	**None of above**	**544**	**10.80**
Total		**5040**	**100.00**

Highlights

11% patients – said None (company / drug authority / doctor)
Rest 89% – said company (34%), Drug Auth (6%), Doctor (35%) responsible for safe med.

Conclusion

- Current level of Knowledge, attitude/awareness and perception /practices **(KAPs) of Indian patients** towards ADRs & ADR reporting **are satisfactory**
  - 43% patients – aware of term side effects
  - 21% patients – had idea about ADR centres
  - 17% patients – reported ADRs to ADR centres
  - 56% patients – informed doctor / pharmacist / chemist after experiencing ADR
- Encouraging facts in favour of direct reporting of ADRs by patients
  - 17% reported ADRs to ADR centres
  - **89%** said **company, Drug Auth & Doctor-singly or jointly responsible for safe medicine**
- So there are hopes that patients (the direct consumers of medicine) can be involved in direct reporting of ADRs to ADR monitoring centres with appropriate training to
  - Enhance awareness
  - Impart knowledge on procedure of direct reporting of ADRs to Monitoring Centres

Conclusion (Contd.)

Further our survey revealed the following changes in approach of patients after educating them to the word “ADR” and related topics

- Informed doctor / pharmacist / chemist about ADR
  - Before 56% .. after 88%
- Collect information about medicine from Doctor
  - Before 28% …... after 30%

Thus there were positive changes in KAP related parameters indicating that the gain in knowledge during conduct of survey just because of knowledge gained by virtue of discussion

This prompted us to recommend certain training related programs to make

1. Patients competent enough to report ADRs directly to ADR Monitoring centres & thus
2. Improve reporting of ADR and
3. Resolve the issue of under reporting to some extent

Recommendations

Drug Authorities, Doctors, Health care professionals to take following activities

- Impart training on
  - awareness on ADRs & ADR reporting
  - Importance of such reporting to Drug authorities in approving best medicine
  - Procedures of reporting ADRs directly to ADR Monitoring centres
- Continuous awareness programs at regular intervals
- Encourage to submit ADR reports under their guidance in schools, colleges, offices & wherever possible

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Thank You !