Quest Journals
Journal of Medical and Dental Science Research
Volume 11~ Issue 8 (2024) pp: 37-44
ISSN(Online) : 2394-076X ISSN (Print):2394-0751
www.questjournals.org

Research Paper

Completeness and Quality of ADR reports published in Leading Biomedical Journals

[1](Dr Sheeraz Sarwar *Senior Resident Department of Pharmacology AIIMS Vijaypur)*
[2](Dr Tania Nazir *Senior Resident Department of ENT GMC Doda)*
[3](Dr Safeena Sarwar *Senior Resident Department of Gynae and Obs ASCOMS)*
[4] (Dr Vishal R Tandon *Professor Department of Pharmacology GMC Jammu)*
[5] (Dr Sapna Gupta *Associate Professor Department of Pharmacology GMC Jammu)*
Corresponding Author Dr Sheeraz Sarwar

ABSTRACT:- *To study the completeness of ADR reports published in leading Indian biomedical, pharmacological or medical journals.The quality and completeness of published ADR reports in leading Bio Medical Journals can prove very vital in the effective implementation of drug safety programmes in the form of PvPI in the country. It will further, go long ways to assure the quality assurance of PvPI not only at National Coordination Centre but also at the respective AMC level.*
KEYWORDS: *Adverse effects,Biomedical journals,Pharmacovigilance*

R*eceived 01 Aug., 2024;* ***R****evised 08 Aug., 2024;* ***A****ccepted 10 Aug., 2024 © The author(s) 2024.*
P*ublished with open access at* ***www.questjournas.org***

I. INTRODUCTION:-

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem **(WHO, 2006).**
According to the World Health Organization (WHO), an ADR is defined as a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or the modifications of physiological function **(WHO, 2007).**

Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality, some of which are identified after marketing. The reporting of ADR should be improved as it's very important in improving patient safety thereby reducing morbidity and mortality, hence taking off some load on the Health care providers **(Thakare VS et al, 2019).**

Currently, over 700 adverse drug reactions (ADR) monitoring Centres (AMCs) in India have been recognized for monitoring and reporting any adverse drug reactions. All the authorized centres fill and upload ADR reports into VigiFlow which is the World Health Organization-Uppsala Monitoring Centre's (WHO-UMC) web-based system to collate ADRs worldwide. It's the ADR form through which, all the patient's related information is captured, and also serves as a source document. This source document after entering into VigiFlow gets converted into Individual Case Safety Report (ICSR). It is these ICSRs which are checked by the NCC for signal generation **(Mahajan MM et al, 2018).**

Further, the various biomedical journals publish ADR-reported case reports which can prove very useful and helpful to PvPI as well as to the prescriber to enhance their education and knowledge which will have a positive impact in enhancing drug safety in day-to-day clinical practice.

Usually, adverse drug reactions which are rare, unusual, severe, serious and fatal and the ones which are resultant of medication errors or drug interactions carry academic and research interest. It has been seen and reported that many a time these reports are not reported to PvPI and are published in leading biomedical journals **(Kahkashan I et al, 2017).** However, these rare, unusual, serious, fatal ADRS are very important for PvPI to identify signals of new or old drugs **(Vivekanandan K et al, 2015)** but it has been widely reported that the published drug-related case reports often do not follow guidelines and thus, poor quality of these published reports fails to serve the purpose to PvPI.

Further, the poor quality of published case reports continues to happen in spite of the availability of joint recommendation guidelines of the International Society of Epidemiology and International Society of

Pharmacovigilance as well as CARE **(Riley DS et al, 2017)** guidelines for submitting adverse event reports **(Kelly WN et al, 2017).**

Thus, the quality and completeness of ICSR as well as quality published ADR reports in leading Bio Medical Journals can prove very vital in the effective implementation of drug safety programmes in the form of PvPI in the country. It will further, go long ways to assure the quality assurance of PvPI not only at NCC but also at the respective AMC level. Hence, the current study was planned.

Primary Objective:-

To study the completeness of ADR reports published in leading Indian biomedical, pharmacological or medical journals

STUDY DESIGN: - A descriptive observational retrospective analysis

The current descriptive observational retrospective study was done after the necessary IEC permission and permission of the ADRM centre.

Method for assessing the completeness of information in biomedical journals

For critically evaluation of the quality of Adverse drug reaction published case reports in three leading Indian open access peer reviewed journals indexed in Medline, Embase, Scopus in the fields of Pharmacology and pharmaco therapeutics and Medicine and allied subjects (Indian Journal of pharmacology, Journal of pharmacology and pharmacotherapeutics and Journal of the association of Physicians of India) with pharmacovigilance as a scope for the last three years was included for such analysis. The data was retrieved as per the partial modification of guidelines recommended by the International Society of Pharmacoepidemiology and International Society of Pharmacovigilance joint recommendations/guidelines for submitting adverse drug reactions for publication use to critically analyze the quality of medical contents of published case reports **(Kelly WN *et al,* 2017)**.

The following scale was used for such analysis:-

1. Title of the report
2. Patients demographic (age, sex, weight, height, race, ethnicity, BMI and occupation)
3. Current health status (Disease or symptoms being treated with the suspected drug, duration of illness, the severity of disease/symptoms)
4. Medical history relevant to an adverse event, reaction or exposure to drug products or class, underlying risk factors, previous therapy of active disease, history of alcohol, tobacco or substance abuse
5. Physical exam (abnormal physical or lab findings, off-label drug use, baseline lab findings and pertinent negative physical findings)
6. Patients disposition (Presence or absence of death, life-threatening circumstance, hospitalization, prolonged hospitalization or significant disability)
7. Suspected drug (generic name, drug dosage, duration route formulation and indication, manufacturer details, expiry date, batch number)
8. Dosage (approximate dosage regimen, duration of therapy start and stop date of the drug, drug concentration and restart dates)
9. Administration drug reaction interface (Therapy duration before the adverse event)
10. Concomitant therapies (description of start & stop date, dose of concomitant therapies and indication for which therapies are used)
11. The rationale of publishing case reports (Mentioned or not mentioned)(Rare/unusual/usual or not mentioned)
12. Naranjo scale used or not used
13. WHO-UMC scale used or not used
14. Severity scale used or not
15. Temporal relationship clear or not clear
16. Preventability scale applied or applied
17. Dose-response relationship studied or not studied
18. SOPs of PvPI followed or not followed (unique Id number mentioned or not mentioned)
19. Pictorial evidence present /not resent/not required
20. Drug level estimation done or not done
21. Information about de-challenge and re-challenge
22. Adverse event description of adverse events with reference to medical contents adequate or not adequate
23. Diagnostic procedure performed to confirm the final diagnosis or not and specific treatment of adverse event and its outcome mentioned or not

24. Discussion includes the presence or absence of evidence supporting causal link (temporal relationship, de-challenge, re-challenge, objective evidence)

Biological Plausibility:-

- Discussion of previous reports of adverse events in biomedical journals
- Discussion of explanation /possible mechanism
- Discussion of progress or planned clinical trial mentioned or not

25. Type of reaction with reason in its support mentioned or not

Each field was given a score of 0.04 and the total score was computed as

0.04 X 25 =1 Total score

In case any single element is missing information for more than 50% of the fields the default scoring will be zero. For the purpose of quantitative and qualitative assessment/grading of published case reports in various biomedical journals after computing the score for each ADR form under evaluation year wise was made and each report was categorized both quantitatively and qualitatively as per the following grading mentioned below:-

F) Complete score (1)
G) Well documented (0.75 - 1)
H) Very good documentation (0.5-0.75)
I) Poor (0.25-0.5)
J) Very poor documentation (<0.25)

STATISTICAL ANALYSIS:-

Descriptive statistical analysis was carried out with the help of computer software SPSS v 15 for windows. The data was retrieved qualitatively and quantitatively and was expressed n (%) as well as mean ±SD.

The "Chi-square test" was applied for some of the parameters expressed as n (%) to prove their statistical significance and the relevant "student t-test" was applied for the data expressed mean ± SD to prove their statistical significance as per their variation between different years and for subgroup analysis carried in the study. The p-value <0.05 was considered significant.

ASSESSMENT OF THE COMPLETENESS OF INFORMATION IN BIOMEDICAL JOURNALS:-

In all the 100 case reports assessed, title of the report, age of the patient was found to be documented in all the ICSRs (100%).

Whereas the sex of the patient, disease vs. symptoms being treated, duration of illness, the severity of the disease were found to be 'Well documented 'in 98%, 93%, 89% and 88% of the case reports evaluated.

Similarly, the parameters like weight, height, race, ethnicity, BMI and occupation of the patient was very poorly documented in 7%, 4%, 11%, 17%, 4% and 0% of the published case reports respectively**. (Table no. 1 a)**

Table No. 1 a:-Assessment of the completeness of information in biomedical journals

Parameter	Number (%)	Statistical value
1. Title of the report documented Vs. not documented	100(100%) Vs. 0(%)	Chi square=199.3807DF=1,Pvalue<0.00001
2a. Age documented Vs. not documented	100(0%) Vs. 0(%)	Chi square=199.3807DF=1Pvalue<0.00001
2b. Sex documented Vs. not documented	98(98%) Vs. 2(%)	Chi square=184.32,DF=1,Pvalue<0.00001
2c. Weight documented Vs. not documented	7(7%) Vs. 93(%)	Chi square=147.92,DF=1,P<0.00001
2d. Height documented Vs. not documented	4(4%) Vs. 96(%)	Chi square=169.28,DF=1,P<0.00001
2e. Race documented Vs. not documented	11(11%) Vs. 89(89%)	Chi square=121.68,DF=1,P<0.00001
2f. Ethnicity documented Vs. not documented	17(17%) Vs. 83(83%)	Chi square=87.12,DF=1,P<0.00001
2g. BMI documented Vs. not documented	4(4%) Vs. 96(96%)	Chi square=169.28, DF=1, P<0.00001
2h. Occupation documented Vs. not documented	0	Chi square=199.3807 DF=1,P value<0.00001
3a. Disease Vs. Symptoms being treated documented Vs. not documented	93(93%) Vs. 7(7%)	Chi square=147.92,DF=1,P<0.00001
3b. Duration of illness documented Vs. not documented	89(89%) Vs. 11(11%)	Chi square=121.68,DF=1,P<0.00001
3c. The severity of disease documented	88(88%) Vs. 12(12%)	Chi square=115.52, DF=1, P<0.00001

Vs. not documented		

Table number 1 b suggests that the presence or absence of death, life threatening circumstances were found to be documented in all case reports published. (100%)
Whereas the abnormal physical or lab findings, has been documented as 'Well documented' in 88%, of the evaluated case reports.
Whereas the treatment of exposure to the drug, product or class, baseline lab findings, and hospitalization, prolonged hospitalization or significant disability has been documented as 'Very good' in 72%, 73%, and 70% of the evaluated case reports respectively.
Whereas medical history relevant to the adverse event, underlying risk factors, history of alcohol/ substance abuse, and pertinent negative physical findings were documented as 'Poor' in 38%, 37%, 31%, and 48% of the evaluated case reports respectively.
Whereas previous therapy of active disease and off-label drug use has been documented as 'very poor' in 19% and 0% of the evaluated case reports respectively. **(Table no. 1 b)**

Table No. 1 b:- Assessment of the completeness of information in biomedical journals

Parameter	Number (%)	Statistical value
4a. Medical history relevant to Adverse event documented Vs. not documented	38(38%) Vs. 62(62%)	Chi square=11.52, DF=1, P<0.000689
4b. Treatment or exposure to the drug, product or class documented Vs. not documented	72(72%) Vs. 28(28%)	Chi square=38.72, DF=1, P<0.00001
4c.Underlying risk factors documented Vs. not documented	37(37%) Vs. 63(63%)	Chi square=13.52, DF=1, P<0.000236
4d. Previous therapy of active disease documented Vs. not documented	19(19%) Vs. 81(81%)	Chi square=76.88, DF=1, P<0.00001
4e. History of alcohol, tobacco or substance abuse documented Vs. not documented	31(31%) Vs. 69(69%)	Chi square=28.88, DF=1, P<0.00001
5a. Abnormal physical or lab findings documented Vs. not documented	88(88%) Vs. 12(12%)	Chi square=1115.52,DF=1,P<0.00001
5b. Off-label drug use documented Vs. not documented	1(1%) Vs. 99(99%)	Chi square=199.3807 DF=1 P value=0.00001
5c. Baseline lab findings documented Vs. not documented	73(73%) Vs. 27(27%)	Chi square=42.32, DF=1, P<0.00001
5d. Pertinent negative physical findings documented Vs. not documented	48(48%) Vs. 52(52%)	Chi square=0.32, DF=1, P<0.571608
6a. Presence of death or life threatening circumstances documented Vs. not documented	51(51%) Vs. 49(49%)	Chi square=0.08 DF=1 P<0.77729
6b. Hospitalization, prolonged hospitalization or significant disability documented Vs. not documented	70(70%) Vs. 30(30%)	Chi square=32,DF=1,P<0.00001

Table number 1 c suggests that generic name of the drug was found to be documented in all case reports published. (100%)
Whereas the drug dosage and duration, indication of the suspected drug use, approximate dosage regimen, start and stop date of the drug, duration of therapy and therapy duration before adverse event, has been documented as 'Well documented' in 76%, 88%, 92%, 84%, 93%, 91% and 89% of the evaluated case reports respectively.
Whereas route of the suspected drug, formulation, and concomitant therapies has been documented as 'Very good' in 60%, 65%, and 56% of the evaluated case reports respectively.
Whereas manufacturers details, expiry date of the suspected drug, batch number, drug concentration and restart dates has been documented as 'very poor' in 2%, 6%, 3%, 11% and 16% of the evaluated case reports respectively.**(Table no. 1 c)**

Table no. 1 c:- Assessment of the completeness of information in biomedical journals

Parameter	Number (%)	Statistical value
7a. Generic name documented Vs. not documented	100(100%) Vs. 0(0%)	Chi square=199.3807 DF=1 P value=0.00001
7b. Drug Dosage documented Vs. not documented	76(76%) Vs. 24(24%)	Chi square=54.08,DF=1,P=0.00001
7c. Duration documented Vs. not documented	88(88%) Vs. 12(12%)	Chi square=115.52,DF=1,P=0.00001
7d. Route documented Vs. not documented	60(60%) Vs. 40(40%)	Chi square=8,DF=1,P=0.004678

7e. Formulation documented Vs. not documented	65(65%) Vs. 35(35%)	Chi square=54.08,DF=1,P=0.00001
7f. Indication documented Vs. not documented	92(92%) Vs. 8(8%)	Chi square=141.12,DF=1,P=0.00001
7g. Manufacturer's details documented Vs. not documented	2(2%) Vs. 98(98%)	Chi square=184.32,DF=1,P=0.00001
7h. Expiry documented Vs. not documented	6(6%) Vs. 94(94%)	Chi square=54.08,DF=1,P=0.00001
7i. Batch Number documented Vs. not documented	3(3%) Vs. 97(97%)	Chi square=176.72,DF=1,P=0.00001
8a. Approximate dosage regimen documented Vs. not documented	84(84%) Vs. 16(16%)	Chi square=92.48,DF=1,P=0.00001
8b. Duration of therapy documented Vs. not documented	91(91%) Vs. 9(9%)	Chi square=140.2408,DF=1,P=0.00001
8c. Start and stop date of drug documented Vs. not documented	93(93%) Vs. 7(7%)	Chi square=54.08,DF=1,P=0.00001
8d. Drug concentration level documented Vs. not documented	11(11%) Vs. 89(89%)	Chi square=121.68,DF=1,P=0.00001
8e. Restart dates documented Vs. not documented	16(16%) Vs. 84(84%)	Chi square=92.48,DF=1,P=0.00001
9. Therapy duration before adverse event documented Vs. not documented	89(89%) Vs. 11(11%)	Chi square=121.68, DF=1, P=0.00001
10. Concomitant therapies documented Vs. not documented	56(56%) Vs. 46(%)	Chi square=1.9608,DF=1,P=0.161429

In table no. 1 d diagnostic procedures performed and discussion of the ADR has been documented as 'Well documented' in 96% the evaluated case reports.

Whereas rationale of the published case reports has been documented as 'Very good' in 55% of the evaluated case reports.

Whereas naranjo scale, temporal relationship, pictoral event, information about de-challenge and re-challenge, adverse event description with refrence to medical contents and type of the reaction were documented as 'Poor' in 26%, 27%, 37%, 40%, 32% and 27% of the evaluated case reports respectively.

Whereas WHO-UMC scale, severity scale, preventability scale, dose response relationship, SOPs of PvPI, drug level estimation, has been documented as 'very poor' in 3%, 2%, 0%, 8%, 4% and 2% of the evaluated case reports respectively.**(Table no. 1 d)**

Table No. 1 d:- Assessment of the completeness of information in biomedical journals

Parameter	Number (%)	Statistical values
11. Rationale of publishing case report documented Vs. not documented	55(55%) Vs. 45(45%)	Chi square=2, DF=1, P=0.157299
12. Naranjo scale documented Vs. not documented	26(26%) Vs. 74(74%)	Chi square=46.08,DF=1,P=0.00001
1. WHO-UMC scale documented Vs. not documented	3(3%) Vs. 97(97%)	Chi square=54.08,DF=1,P=0.00001
2. Severity Scale documented Vs. not documented	2(2%) Vs. 98(98%)	Chi square=184.32,DF=1,P=0.00001
3. Temporal relationship documented Vs. not documented	27(27%) Vs. 73(73%)	Chi square=42.32,DF=1,P=0.00001
4. Preventability Scale documented Vs. not documented	0(0%)Vs. 100()100%	Chi square=199.3807 DF=1 P value=0.00001
5. Dose-response relationship Studied documented Vs. not documented	8(8%) Vs. 92(92%)	Chi square=141.12,DF=1,P=0.00001
6. SOPs of PvPI documented Vs. not documented	4(4%) Vs. 96(96%)	Chi square=54.08,DF=1,P=0.00001

7. Pictoral event present documented Vs. not documented	37(37%) Vs. 63(63%)	Chi square=13.52,DF=1,P=0.000236
8. Drug level estimation documented Vs. not documented	2(2%) Vs. 98(98%)	Chi square=184.32,DF=1,P=0.00001
9. Information about De-challenge and re- challenge documented Vs. not documented	40(40%) Vs. 60(60%)	Chi square=25.92,DF=1,P=0.00001
10. Adverse event description with reference to medical contents is adequately documented Vs. not documented	32(32%) Vs. 68(68%)	Chi square=141.12, DF=1, P=0.00001
11. Diagnostic Procedures performed documented Vs. not documented	96(96%) Vs. 4(4%)	Chi square=169.28,DF=1,P=0.00001
12. Discussion documented Vs. not documented	96(96%) Vs. 4(4%)	Chi square=169.28,DF=1,P=0.00001
13. Type of reaction documented	27(27%) Vs. 73(73%)	Chi square=67.28, DF=1, P=0.00001

In the case of biological plausibility **(Table no. 2),** the discussion of the previous reports of an adverse event in biomedical journals were documented as poor in 49% of the case reports studied.
The discussion on explanation /possible mechanism was documented as very good in 73% of the case reports.
However, the discussion of the progress of planned clinical trial has been documented as very poor in 6% of the case reports studied.

Table no. 2:- Assessment of Biological Plausibility

S No.	Number (%)	Statistical value
1. Discussion of previous reports of an adverse event in biomedical journals documented Vs. not documented	49(49%) Vs. 51(51%)	Chi square=0.08, DF=1, P=0.777297
2. Discussion on explanation /possible mechanism documented Vs. not documented	73(73%) Vs. 27(%)	Chi square=42.32, DF=1, P=0.00001
3. Discussion of progress or planned clinical trial mentioned documented Vs. not documented	6(6%) Vs. 94(94%)	Chi square=154.88, DF=1, P=0.00001

Grading of completeness score of case reports published in Biomedical Journals:-
Out of all the case reports evaluated 62% of them were graded as 'Very good documentation' (0.5-0.75), and 38% were graded as 'Poor documentation (0.25-0.5).
However, none of the reports were graded as 'Complete', 'Well documented 'or with 'Very poor documentation'. Their P-value was found significant<0.00001**. (Table no. 3)**

Table No. 3:- Grading of Completeness Score of Case Reports Published in Biomedical Journals

S No.	Number of ICSRs	Total	Percentage	Mean±SD
1. Complete(1)	0	100	0%	0.51±0.07 i.e. very good documentation
2. Well documented(.75-1)	0	100	0%	
3. Very good documentation(0.5-0.75)	62	100	62%	
4. Poor(0.25-0.5)	38	100	38%	

5. Very Poor documentation(<0.25)	0	100	0%	

Completeness of information in Biomedical Journals:-

The findings of the current study suggested that the ICSRs published have a Mean±SD completeness score of 0.50±0.97 thereby suggesting 'poor documentation'. The study revealed that weight, height, race, ethnicity, BMI occupation, medical relevant history, underlying risk factors, previous therapy details, history of alcohol abuse/ substance abuse, manufacturers details, expiry, batch number drug concentration levels and restart dates were poorly documented

The most important parameters mandatory for any case reports like Naranjo, WHO, severity scale, temporal relationship, preventability scale information, pictorial evidence, drug levels estimation based evidence, information about de-challenge and re-challenge, availability of similar information in the literature and type of the reaction were poorly documented in the current study.

The results are in agreement with one of our previous studies of **Kahkashan I *et al,* 2017** where as Naranjo and WHO scales were not used in 21.88% and 56.25% of the cases respectively. The severity and preventability scales were not applied in 90.63% and 94.79% of the cases, the temporal relationship was not clear in 4.21% of the cases while medical contents were inadequate in 42.71% of the cases. Further, in their study in 83.3% of cases dose-response relationship was not seen, pictorial evidence was also lacking in 48.9% and drug estimation was found missing in 92.7% of the cases. Information regarding the possibility of other offending drugs was found in 53.3% of the cases. In 19.79% of cases, the investigations were present but were inadequately documented thereby this study like our study suggested on the same lines that the quality and medical content of ADR reports in Indian Biomedical journals were inadequate in various aspects which need improvisation and there is a high time that uniform guidelines be framed and proposed by PvPI for all Indian Biomedical journals to enhance the completeness of the information.

A study by **Hotwani J *et al,* 2018** found that most of the patient-related and ADR -related details were adequately reported (>90%) whereas the title, most of the drug-related details and highly desired parameters were reported poorly (<90%). The completeness of ADR case reports ranged from 10/17 to 16/17 for required parameters and from 2/13 to 11/13 for highly desired parameters.

Our study highlights the deficiencies in published case reports, thereby suggesting the researchers to follow the ISPE and ISOP guidelines while writing an ADR case report and journal editors to incorporate minimum publishing requirements for publishing ADR case reports to gain the most out of them.

Impicciatore P *et al,* 2010 reported that in 92% of the case reports, the patient's medical history pertinent to the ADR was mentioned. In 11% of the cases, the proprietary name of the suspected medicine was mentioned; the duration, dosage, route, and formulation were all recorded in 87%, 85%, 37%, and 21% of the incidents, respectively. In 71% of the reports, concurrent therapies were mentioned. Details on management (99%), time course (97%) and diagnostic tests (95%) were included in the description of the ADR, while final outcome and seriousness were covered in 73% and 52% of the reports, respectively. In 70% of the case reports, a potential ADR mechanism was mentioned. Causality assessment was reported in 81%, and rating scales to support the causal link were used in 20% of the reports.

The findings of this study show that published ADR case reports, especially those coming from non-specialized journals still lack important necessary for comprehensive evaluation. The results of the current study are partially in agreement with the above study in some aspects where as they showed a discrepancy in others.

Calvo EC *et al,* 2008 reported that the data elements were more often incomplete regarding dose, length of the treatment, as well as the length of the adverse reaction. Only one-third of the published case reports included full information, the results of which are partially in agreement with the above study in some aspects.

Sempere E *et al,* 2006 documented that there were no differences in the mean minimum publication criteria in their study. The causal relationship was acceptable; the documentation quality was high, with few unknown reactions and ADRs to recently marketed drugs. The results of our study are not in agreement with this study. The possible reason for the contrary result may be different nature, method & design of the study and variation in the outcome parameter in the current study.

A similar scenario like our study was reported by **Kelly WN, 2003** in a descriptive analysis of 1520 ADE case reports published in English journals over a 20-year period and suggested that patient variables were reported >90% of the time. Most of the relevant ADR variables were reported most often. Added information for drug interactions, medication errors, and allergic drug reactions were reported 61-99% of the time. Less than 1% of ADE reporters objectively assessed the probability of the ADE.

In a study conducted by **Venulet *et al,* 1982** inclusion of such basic, but relevant, items, e.g age and doses, duration of treatment, and galenic form has been seen in only 19% of the articles included in their study. The findings of this study were in agreement with our study thereby suggesting a need to improve the data elements content of published adverse drug reactions case reports.

The current study revealed that both the quality of ICSRs with regard to completeness score as well as case reports published in Indian biomedical journals was poor.

As we all are aware that the biggest challenge besides under reporting of ICSRs, the quality of ICSR reported also is a challenge to the current PvPI programme. The Incomplete information not only increases the work load at IPC regarding the correct causality assessment understands the nature and type of adverse drug reaction thereby huge negative impact on Pharmacovigilance programme, further can account for delay in quality signal or drug safety alerts generated at IPC and Drug Regulatory authority level.

Further despite the availability of joint recommendations guidelines of International Society of Epidemiology and International Society of Pharmacovigilance as well as CARE guidelines still the adverse drug reaction related reports continue to get publish in leading in Biomedical Journals. The quality of case reports published in Biomedical journals is an important source of rare, unusual adverse drug reactions which many times first appear in Biomedical journals and subsequently reported to IPC as an inherent tendency of the researchers and clinicians.

Thereby, proposing an urgent and dire need at all possible levels i.e. at individuals AMC levels, at PvPI levels, and at editors, of various biomedical journals to create awareness and frame guidelines in direction of Good Pharmacovigilance practices, in the field of Pharmacovigilance as any incomplete information provided by Vigiflow or by the medium of Biomedical journals can adversely affect the Pharmacovigilance programmes, particularly by delaying the signal generation.

In light of the results of the current study will propose following recommendations for authorities:-

a. Periodic check of Completeness Score of all ICSR at respective AMC as well as IPC level.

b. Any poor or very poor document ICSR should not be allowed to upload in the Vigiflow and reverted back for completeness to respective AMC centre.

c. The IPC should frame guidelines for biomedical journals keeping in view of mandatory requirement of information desired under PvPI programme.

d. The SOP on publications already framed and proposed by IPC be executed at all levels in letter and spirit.

e. Creating awareness for completeness of ICSRs and how to publish an ideal case report for rare and unusual drug effect be created at all possible levels.

II. Summary:-

Completeness of Information in Biomedical Journals:-

- While evaluating case reports it was revealed that the parameters like title, age, sex, details of disease/symptoms, duration of illness, the severity of disease, abnormal physical / Lab findings, generic name of the drug, dosage, duration, indication regimen, start and stop date of therapy, the diagnostic procedure performed and appropriate discussion were found **Well documented** and above.
- Whereas weight, height, race, ethnicity, BMI occupation, medical relevant history, underlying risk factors, previous therapy details, history of alcohol abuse/ substance abuse, manufacturers details, expiry, batch number drug concentration levels and restart dates were **poorly documented**
- The most important parameters mandatory for any case reports like Naranjo, WHO, severity scale, temporal relationship, preventability scale information, pictorial evidence, drug levels estimation based evidence, information about de-challenge and re-challenge, availability of similar information in the literature and type of the reaction were **poorly documented** in the current study.
- While grading the completeness of case reports it was found that the majority of them fall between poorly documented and very good documentation and the Mean ± SD score of ICSRs published in biomedical journals was found to be 0.50±0.97 thereby suggesting **poor documentation**.

III. Conclusion:-

- The mean ICSR score of the reports published in Biomedical journals also revealed to have ‘very good documentation’, thereby indicating the need for good Pharmacovigilance practices to be made mandatory both for PvPI centres across the country and also guidelines to be framed for Biomedical journals.