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Original Article

Pharmacology Section

Comparison of Two Completeness Scoring Tools for Adverse Drug Reaction Forms: A Cross-over Open Label Pilot Study at a Pharmacovigilance Monitoring Centre in Navi Mumbai, India

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ABSTRACT

Introduction: Completeness of Adverse Drug Reaction (ADR) reports is critical for effective pharmacovigilance. In India, different scoring tools are used to evaluate report quality, but little is known about their comparative performance in terms of time efficiency and scoring logic.

Aim: To compare the two available completeness scoring tools- Tool I (Modified from National Coordination Centre (NCC) by Mahajan M et al.,) and Tool II {(A scale prepared by experts from one of the ADR Monitoring Centres (AMC)} for ADR forms with respect to the time required for assessment and the categorisation of completeness scores.

Materials and Methods: The present comparative, cross-over, open label pilot study was conducted at an AMC in Navi Mumbai, Maharashtra, India, between October 2024 to March 2025. This was a pilot study to check the feasibility so that a large, multicentric sample size could be conducted in near future. Thirty randomly selected ADR forms were independently evaluated by two professionals using two scoring tools: Tool I (Modified NCC by Mahajan M et al.,) and Tool II (Kuchya SK and Shrivastav S). A three day washout period was implemented. Completeness score distribution and time taken were analysed by using Mann-Whitney U test.

Results: Tool I was more time-efficient than Tool II (62.4±8.5 vs 74.4±7.2 seconds; p<0.001). Using Tool I, 27 (90%) of reports were found to be >75% complete versus 25 (83.3%) using Tool II. Using Tool II, 5 ADR forms were in the 5 (50-75%) completeness category. The most frequent ADRs were rash 8 (26.6%) and itching 5 (16.6%), primarily associated with antimicrobials 12 (40%).

Conclusion: Both tools were effective, but Tool I (Modified NCC) was significantly more time-efficient. The difference in scoring distribution highlights the need for a standardised tool to optimise ADR reporting practices.

Keywords: Completeness score, Drug related problems, Individual safety report, Quality of life

INTRODUCTION

The ADRs are defined as any unfavourable response to an administered drug. ADR-related hospitalisations contribute substantially to the economic burden and reduced quality of life for patients in both developing and developed countries [1]. Reporting ADRs is essential to understand and analyse these events, and also to reduce the morbidity and mortality caused by drug-related problems [1,2]. Although pharmacovigilance programs have improved drug use patterns, under-reporting of ADRs remains a major challenge [3-5]. This issue is consistently observed across healthcare institutions [3]. ADR reports submitted to the World Health Organisation (WHO) via the VigiFlow system play a crucial role in the interpretation of drug safety data and the implementation of regulatory measures [6,7]. Incomplete data within ADR reports significantly impairs the ability to interpret these forms effectively. Therefore, assessing the completeness of ADR reports is vital to the success of pharmacovigilance programs [8,9].

With thoroughly complete ADR forms, the signal detection process can be expedited. Thus, conducting quality checks at the source document level- the initial step of the signal detection pipeline is beneficial not only at the AMC level but also at national and global levels [7,10,11]. Several published tools are available to calculate completeness scores [9,10,12-14]. Identifying differences in scoring logic and practical feasibility can help improve the overall quality of ADR documentation [9,12-14].

At present, validated completeness scoring systems are available only for Individual Case Safety Reports (ICSRs). Moreover, there are no recommendation for using specific completeness score tool at AMC level. The most widely recognised tool is VigiGrade, developed by the World Health Organisation (WHO)- Uppsala Monitoring Centre (UMC), which assigns weighted scores to ICSRs based on the presence of critical variables such as patient details, drug information, and temporal association of the event. The National Coordinating Centre (NCC) uses a completeness score for assessment of quality of ADR submissions [15]. In 2016, the NCC introduced a locally developed scoring tool that assigns weighted values to each form field and generates a completeness score using a multiplicative model [10]. This has shown measurable improvements in the quality of ADR reporting over time.

A comprehensive literature search performed using various search engines along with other resources from NCC-PvPI and the WHO-UMC to explore the availability of a completeness scoring systems for ADR forms yielded two tools, both designed for ADR source documents [12,13]. There are no previously published studies directly comparing the time efficiency of ADR assessment tools which highlights uniqueness of this work. Thus, the present study aimed to compare two completeness scoring tools for ADR forms with respect to the time required for scoring and categorisation of completeness scores.

MATERIALS AND METHODS

The present comparative cross-over open label pilot study was conducted at an AMC after approval from the Institutional Ethics Committee of D Y Patil School of Medicine (DYPSOM), Navi Mumbai, Maharashtra, India (IEC Ref. No: DYP/IECBH/2025/145). The study was carried out from October 2024 to March 2025.

ADR form selection: The ADR reports submitted during the study period were screened for presence of essential information i.e., patient details, event details, drug details, and reporter details. Thirty ADRs forms satisfying the eligibility criteria of completed forms submitted to AMC of DYPSOM, Navi Mumbai were selected using a simple random sampling method. Incomplete, illegible, or poorly filled forms were excluded to ensure data accuracy and reliability.

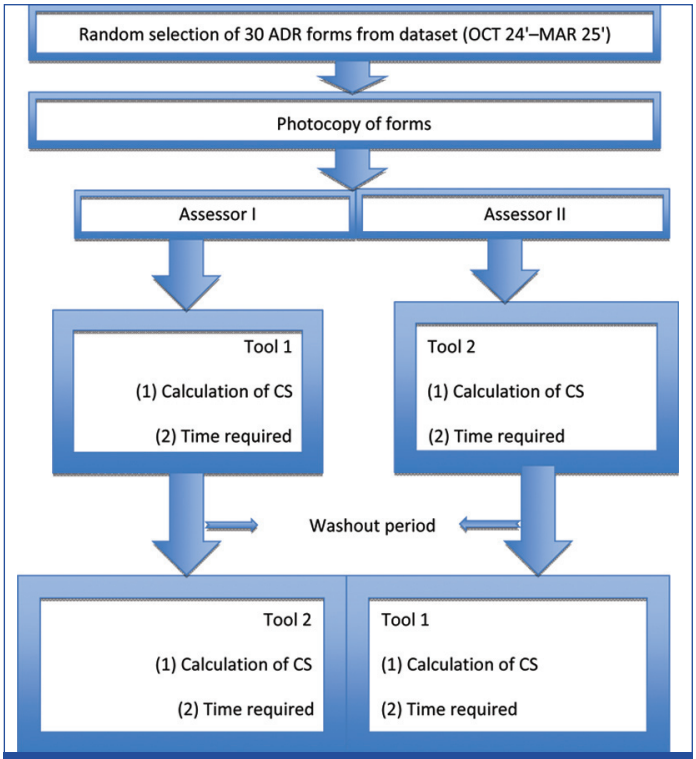
Study Procedure

ADR forms were independently assessed by two trained professionals. Assessment parameters were calculation of completeness scores and the time required using two different scoring tools [12,13].

Tool I- Mahajan M et al., made a minor modification to the validated weighted scoring system developed by the NCC for ICSRs. Since the ADR form lacks fields for case narrative and compliance with SOPs, these were scored zero. In the NCC instrument, the free-text field (test procedure, medical history, additional drug details, sender's comments, reporter's comments) totals one point. As sender's and reporter's comments are absent in the ADR form, they were replaced with dechallenge and rechallenge information, retaining the total score of one. This free-text field corresponds to "Others 1" in the ADR form [13].

Tool II- A filled ADR forms is considered valid for completeness assessment only if all four sections- Patient identifiers, suspected adverse reaction, Suspected medication, and Reporter information contain legible entries [12], as per NCC-PvPI SOP IPC/PvPI/GEN 001/Revision 3/15-5-15. Each section is assigned an equal score of 10, with individual fields weighted according to their importance: mandatory fields receive double the weight of essentially required fields (2:1 ratio). The final score for each field is derived by proportionally distributing the section score based on this weightage system mentioned by Kuchya SK and Shrivastav S [12].

A three-day washout period was observed between using each tool to minimise cognitive recall bias. The sequence numbers of ADR forms were masked to reduce recall and observer bias. Completeness scores were independently calculated by each assessor. The time taken for use of each scoring tool was used as a surrogate for ease of use as shown in [Table/Fig-1]. Causaulity assement for all ADRs was performed using WHO-UMC criteria [16].



[Table/Fig-1]: Assessment of Adverse Drug Reaction (ADR) forms.
ADR: Adverse drug reaction; CS: Completeness score

STATISTICAL ANALYSIS

Data were compiled in Microsoft Excel 2021. Completeness scores were expressed as mean±Standard Deviation (SD). Normality was assessed using the Kolmogorov-Smirnov test. Mann-Whitney U test was used for comparison of scores between two groups. A p-value<0.05 was considered statistically significant.

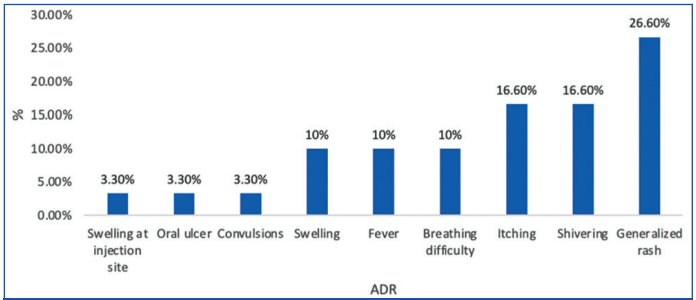
RESULTS

The demographic and clinical characteristics of 30 ADR reports analysed in the study is summarised in [Table/Fig-2]. The median age of the patients was 41 years. In 27 (90%) ADRs, an appropriate action was taken, while 3 (10%) of the forms did not mention any intervention. A total of 25 (83.3%) ADRs had recovered at the time of reporting, 2 (6.6%) were in the process of recovery whereas outcome details were missing in 3 (10%) of the cases. As per the WHO-UMC criteria 23 (76.6%) of ADRs were classified as certainly related to the drug. A total of 5 (16.6%) and 2 (6.6%) were classified as probably, and possibly related to the drug respectively.

Parameters	N (%)
Median (IQR) age (years) (N=23)	41 (23, 56)
Gender	
• Male	14 (46.6%)
• Female	14 (46.6%)
• Not mentioned	2 (6.8%)
Action Taken	
• Yes	27 (90%)
• Not mentioned	3 (10%)
Outcome	
• Recovered	25 (83.3%)
• Recovering	2 (6.6%)
• Not mentioned	3 (10%)
Causality assessment	
• Certain	23 (76.6%)
• Probable	5 (16.6%)
• Possible	2 (6.6%)

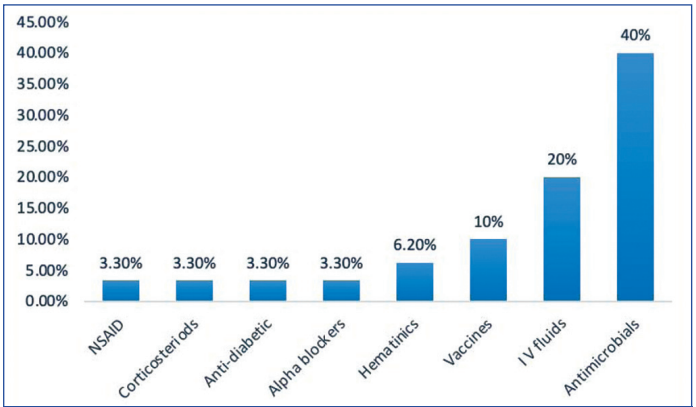
[Table/Fig-2]: Demographic and clinical characteristics of ADR reports (N = 30).

The percentage of distribution of ADRs reported in the study is illustrated in [Table/Fig-3]. Among the reported ADRs, rash 8 (26.6%) was the most frequently reported ADR. Itching and shivering were reported in 5 (16.6%) of cases each. Swelling, fever, and breathing problem were reported in 3 (10.0%) of the ADRs each. Abscess, oral ulcer, and convulsions were reported in 1 (3.3%) patient each.



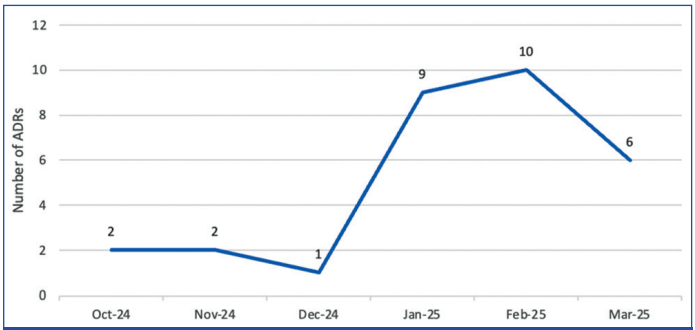
[Table/Fig-3]: Distribution of Adverse Drug Reactions (ADR).
ADR: Adverse drug reaction

Antimicrobials accounted for 12 (40.0%) of reported ADRs. Intravenous fluids were the second most common cause, responsible for 6 (20.0%) of cases. Vaccines contributed to 3 (10.0%) of ADRs. Hematinic accounted for 2 (6.6%), while non-steroidal anti-inflammatory drugs (NSAIDs), steroids, anti-diabetics, and alpha blockers each contributed 1 (3.3%) of the total ADRs [Table/Fig-4].



[Table/Fig-4]: Adverse Drug Reactions (ADR) by pharmacological class.

The number of ADR reports submitted over a six-month period from October 2024 to March 2025 is depicted in [Table/Fig-5]. In October and November 2024, ADR submissions remained constant (2 reports each month). In December 2024 only one report was submitted. In January, February and March 2025, nine, ten and six reports were submitted respectively.



[Table/Fig-5]: Month wise distribution of Adverse Drug Reactions (ADR).

The Tool I required significantly less time for calculating completeness scoring compared to the Tool II (p=0.0002; [Table/Fig-6]).

Scoring tools	Time (Seconds) Mean (SD)	p-value
Tool I	62.43 (8.53)	0.0002
Tool II	74.43(7.17)	

[Table/Fig-6]: Time required for calculating completeness score of two tools.
*Shapiro-Wilk test (p-<0.005) & ** Mann-Whitney U test

As per Tool I, 27 (90%) reports had 75-100% completeness whereas 2 (6.67%) reports were 50-75% complete. A total of 1 (3.33%) report had completeness between 25-50%. No reports were classified in the <25% complete. Tool II also demonstrated 75-100% completeness in 25 (83.33%) ADRs. A total of 5 (16.67%) ADRs forms were in the 50-75% completeness category. No ADR reports scored below 50% [Table/Fig-7].

Parameters	Completeness score				
	<25% (n)	25-50% (n)	50-75% (n)	75-100% (n)	p-value
Tool I	0	1	02	27	0.71*
Tool II	0	0	05	25	

[Table/Fig-7]: Completeness scores by two different tools
*Fisher's-Exact Test

DISCUSSION

The present study evaluated the completeness of ADR reporting forms using two different assessment tools. Using both tool, majority of reports had high completeness (>75%). Tool I yielded marginally more reports in the highest category, whereas Tool II showed slightly better distribution in the 50-75% range. This indicates satisfactory documentation quality consistent with earlier studies by Thakare V et al., and Karande V et al., who reported notable improvements in ADR reporting following structured educational interventions [2,15]. These findings also align with other regional audits that have reported increasing completeness scores over time, reflecting strengthening pharmacovigilance practices in diverse healthcare settings [6,13]. Collectively, these trends underscore the effectiveness of capacity-building measures, feedback systems, and integration of pharmacovigilance into clinical practice as strategies to promote high-quality ADR reporting.

The results demonstrated that Tool II, although effective, was significantly more time-consuming, possibly due to more stringent field-weighting mechanisms that require additional scrutiny. In contrast, Tool I was found to be more pragmatic, as it enabled rapid evaluation without substantial compromise in completeness scoring. This efficiency is of particular importance in high-volume pharmacovigilance settings, where professionals must frequently handle large numbers of ADR reports under time constraints. By facilitating faster assessments, Tool I allows pharmacovigilance personnel to redirect their time toward core activities such as causality assessment, signal management, quality assurance, and follow-up with reporters.

Completeness of ADR forms is essential for ensuring reliable signal detection and robust evaluation of drug safety profiles. Incomplete or poorly documented ADRs reduce the value of ICSRs, thereby limiting their contribution to regional or global pharmacovigilance databases. Largely satisfactory completeness scores suggest a maturing culture of pharmacovigilance reporting. This is aligned with global recommendations by the WHO-UMC, which emphasises not only the necessity of reporting but also the importance of ensuring comprehensiveness and accuracy of submitted data [17]. Variability in pharmacovigilance knowledge and reporting practices highlighted by Prakasam A et al., and Sahu RK et al., can directly influence ADR completeness scores and data quality [18,19].

Similar challenges have been highlighted in evaluations of pharmacovigilance workflow, where balancing completeness with timeliness is critical for ensuring both regulatory compliance and effective safety monitoring [8,12,15]. Although Tool II may remain valuable in academic or audit settings that demands detailed scrutiny, Tool I offers a more practical option for day-to-day operational use. The choice of tool should therefore be guided by the specific context. For instance, Tool I may be useful for efficiency and routine surveillance while Tool II may be a good option when stricter assessments are required for training, research, or detailed evaluation.

Overall, the findings of this study extend the literature by providing new insights into the resource implications of ADR completeness assessment. The observations highlight that the choice of assessment tool directly influences time management - an often overlooked but practically important factor for pharmacovigilance centres.

Limitation(s)

This was a single-center pilot study with a small sample size, limiting the generalisability of the conclusion.

CONCLUSION(S)

Both scoring tools proved valuable for assessing ADR completeness. Tool I (Modified from NCC by Mahajan M et al.,) was more time efficient than Tool II (A scale prepared by experts from one of the ADR Monitoring Centres). Variations in score distribution highlight the need for nationally standardised yet practical scoring frameworks to support better pharmacovigilance practices. Future multicentric studies are recommended to evaluate inter-rater reliability, tool usability, and their influence on signal detection efficiency.

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