# Original Research

# Analysis and Validation of Commonly Used Medicine Information Sources with Reference to WHO Essential Medicine List: An Observational Study

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**ABSTRACT**:
With the flooding of many drugs in market, many irrational drugs and combinations are being prescribed. WHO has set up many standard guidelines to prevent this. The program also involves  essential medicine list formulation and information about drugs. There are many drug information sources but none of them is complete. The present study was conducted for a period of one year in GMC, Jammu to analyse and validate many drug sources. The current study highlights that sources of drug information likely to be used by patients (Wikipedia, Medicinal strips/Package inserts) and healthcare providers (Drug Today/Martindale/MEDLINE) failed to provide complete and adequate drug information. In comparison to National Formulary of India, all these sources significantly provided more inadequate information. National Formulary of India also failed to provide complete/adequate information as per the standards laid down by WHO. Further, these sources significantly varied in providing the drug information. Relatively National Formulary of India, followed by Martindale emerged as better among the all. The current study strongly recommends that all these sources need scientific upgradation, otherwise in the present state it can have negative impact on the drug information seeker.
**Key words:** Drug information, health care, Medicine.

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## INTRODUCTION

With present availability of more than one lakh drug formulations, coupled with continuous inflow of new drugs and molecules in the market, a peculiar situation aptly described as "therapeutic jungle" has crept in. In addition, the flooding of irrational drug combinations as well as lack of standard treatment protocols in some of the hospitals compromise the patient's health ignoring drugs safety. The seriousness of situation is compounded with lack of proper, complete information to the consumers and healthcare professionals. To largely overcome these drawbacks, particularly in a resource limited, under-developed and developing countries, the concept of Essential Drug List was introduced in 1975 by 18th World Health Assembly under the aegis of World Health Organization (WHO). The first model list of essential medicines has undergone revision after every two years since 1977 and the last WHO essential list of medicines was updated in April 2013 [1].

WHO has stressed upon every member country to frame standard treatment guidelines for the most common diseases and complaints prevalent in that country. The healthcare professionals and patients must receive relevant and reliable drug information to ensure patient safety. This program entails essential medicine list formulary to provide information on indication, dosage, adverse effects, contraindications, warning and guidelines for selecting the right medicine for range of clinical conditions.

The choice for drug information source can range from WHO formulary, National formulary, free web-based software, Standard Textbook of Pharmacology, drug reviews [Drug Today, Monthly Index of Medical Specialities (MIMS), Current Index of Medical Specialities (CIMS), Pharmacopeias) and from Cochrane Database, Embase, Pubmed, Pubmed Central and Directory of Open Access Journals (DOAJ).

However, most of these drug information sources, other than indexing agencies, often fail to provide reliable, authoritative, up to date, unbiased, complete scientific drug information. Many studies show conflicting drug information by various drug information sources [2,3,4,5]. Therefore, it becomes imperative to harmonise and validate the commonly used drug information sources in the interest of enhancing pharmacotherapeutics and patient safety.

Though, the studies evaluating different drug information sources and their utility in proving standard complete information has been done in the past [6,7,8,9], but to the best of our knowledge there exist no study which comprehensively compares and validates the most commonly used drug information sources by patients and healthcare providers. Therefore, the current study was conceived with two objectives, first to analyze common medicine information sources used by patients and healthcare providers in acquiring standard, complete, unbiased, authenticated, evidence-based medicine information and secondly to compare any existing variation and validate most commonly used medicine information sources with reference to WHO Essential Medicine List.

## MATERIALS AND METHODS

The study was conducted for a period of one year *w.e.f.* November, 2014 to October, 2015 in the Department of Pharmacology, Government Medical College, Jammu after due administrative and Institutional Ethics Committee permission vide No. IEC/2015/140, dated 19-05-2015.

In the preliminary survey, it was found that commonly used medicine information sources by healthcare providers were Drug Today and Medline, while patients referred product leaflets/package inserts and Wikipedia for enhancing information about medicines. The medicine information sources were validated with Standard Textbook (*Martin Dale – A Complete Drug Reference*) which served as pharmacological standard source. This study also utilized a national reference of medicine information *i.e.* National Formulary, to validate used medicine information sources for the study.

Medicine information domains which were analyzed and compared with the Standard Medicine Information source are generic name of the drug, the brand name, amount of active ingredients per dose, adjuvants, approved therapeutic indications, dosage forms, dosage schedule, side effects/adverse effects information, precautions, contra-indications, warnings, major medicine interactions, pharmacokinetic and pharmacodynamics information, over-dosage, toxicity, special situations, average duration of treatment, dosage for adult and children, route of administration, content and dose for each route, pack size, shelf-life, storage information, description of product and package, evidence/reference [10,11,12,13].

Medicine information domains were analyzed as per WHO parameters and compared with the Standard Medicine Information source. Out of 457 drug formulations mentioned in EML, only 340 drug formulations were studied as same drugs with different formulations were avoided. Adequacy of drug information provided by drug information sources were graded according to WHO *i.e.* complete, adequate, partially adequate and inadequate.

### Statistical Analysis

The data was reported as number/percentage. Chi-square test and other statistical tests were used to evaluate the data. A 'p'-value of $<0.05$ was considered significant. All the analyses were carried out with the help of computer softwares MS Excel and SPSS version 23 for Windows.

**Table 1.** Comparison of Drug Information Data Provided by Drug Information Sources Used by Patients and Healthcare Providers

| Parameters | Wikipedia (n=340) No. (%) | Medicinal Strips/ Package Inserts (n=340) No. (%) | MEDLINE (n=340) No. (%) | Martindale (n=340) No. (%) | Drug Today (n=340) No. (%) | National Formulary of India (n=340) No. (%) |
|---|---|---|---|---|---|---|
| ***Drug Name*** |  |  |  |  |  |  |
| Brand Name | 225 (66.18) | 321 (94.41) | 212 (62.35) | 168 (49.41) | 86 (25.29) | 1 (0.29) |
| Generic Name | 289 (85.00) | 321 (94.41) | 267 (78.53) | 231 (67.94) | 86 (25.29) | 274 (80.59) |
| ***Pharmacological Data*** Pharmacological Effects | 75 (22.06) | 40 (11.76) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Mechanism of Action | 83 (24.41) | 40 (11.76) | 3 (0.88) | 126 (37.06) | 0 (0) | 0 (0) |
| Pharmacokinetic Data | 63 (18.53) | 51 (15.00) | 0 (0) | 99 (29.12) | 0 (0) | 0 (0) |
| Indications | 61 (17.94) | 53 (15.59) | 257 (75.59) | 219 (64.41) | 85 (25.00) | 269 (79.12) |
| ***Clinical Information*** Dosage | 8 (2.35) | 8 (2.35) | 31 (9.12) | 4 (1.18) | 0 (0) | 236 (69.41) |
| Dose Interval | 3 (0.88) | 4 (1.18) | 25 (7.35) | 0 (0) | 0 (0) | 212 (62.35) |
| Average Duration of Treatment | 4 (1.18) | 3 (0.88) | 2 (0.59) | 1 (0.29) | 4 (1.18) | 0 (0) |
| Special Situations | 23 (6.76) | 15 (4.41) | 2 (0.59) | 115 (33.82) | 0 (0) | 0 (0) |
| Contraindication | 50 (14.71) | 14 (4.12) | 3 (0.88) | 155 (45.59) | 4 (1.18) | 194 (57.06) |
| Precautions/ Warnings | 71 (20.88) | 14 (4.12) | 141 (41.47) | 154 (45.29) | 13 (3.82) | 233 (68.53) |
| Adverse Drug Reactions | 238 (70.00) | 58 (17.06) | 213 (62.65) | 176 (51.76) | 85 (25.00) | 254 (74.71) |
| Drug Interactions | 30 (8.82) | 50 (14.71) | 0 (0) | 47 (13.82) | 3 (0.88) | 0 (0) |
| Toxicity | 21 (6.18) | 36 (10.59) | 4 (1.18) | 1 (0.29) | 0 (0) | 0 (0) |
| Over Dose Treatment | 16 (4.71) | 35 (10.29) | 2 (0.59) | 1 (0.29) | 0 (0) | 0 (0) |
| ***Pharmaceutical Information*** Dosage Form | 207 (60.88) | 321 (94.41) | 198 (58.24) | 212 (62.35) | 86 (25.29) | 265 (77.94) |
| Route of Administration | 206 (60.59) | 33 (9.71) | 190 (55.88) | 211 (62.06) | 86 (25.29) | 266 (78.24) |
| Content and Dose for Each Route | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Additives | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Pack Size | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Shelf Life | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (0.29) |
| Storage | 0 (0) | 78 (22.94) | 0 (0) | 0 (0) | 0 (0) | 258 (75.88) |
| Description of Product and Package | 1 (0.29) | 321 (94.41) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| ***Legal Aspects*** Mention of Prescription / Non Prescription Drugs | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Name and Address of Manufacturer | 6 (1.76) | 311 (91.47) | 0 (0) | 4 (1.18) | 2 (0.59) | 4 (1.18) |
| Abridged Prescription Information | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |

**Table 2.** Comparison of Adequacy of Drug Information Provided by Various Sources of Drug Information Used by Patients and Healthcare Providers with Reference to WHO Essential Medicine List (EML)

| Drugs Information as per WHO | Wikipedia (n=340) No. (%) | Medicinal Strips/ Package Inserts (n=340) No. (%) | MEDLINE (n=340) No. (%) | Martindale (n=340) No. (%) | Drug Today (n=340) No. (%) | National Formulary of India (n=340) No. (%) |
|---|---|---|---|---|---|---|
| Complete | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Adequate | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Partially adequate | 124 (36.47) | 108 (31.76) | 10 (2.94) | 218 (64.12) | 12 (3.53) | 167 (49.12) |
| Inadequate | 216 (63.53) | 232 (68.24) | 330 (97.06) | 122 (35.88) | 328 (96.47) | 173 (50.88) |

## RESULTS

Among the drug information sources which were studied, Wikipedia and Medicinal Strips/Package Inserts were assumed to be commonly used by patients as drug information sources, whereas MEDLINE, Martindale, Drug Today were assumed to be commonly used drug information source by healthcare providers.

Analysis of different sources of information revealed that information regarding prescribed/non-prescribed, and abridged prescribed information was not provided by any source. The legal information and name and address of manufacturers was adequately provided only by the medical strips/Package Inserts (311; 91.47%) and was found negligible in other sources. Wikipedia mentioned name and address of manufacturers for 6 (1.76%) drugs only, while 4 (1.18%) drugs each were mentioned by Martindale and National Formulary. Drug Today mentioned name and address of manufacturers only for 2 (0.59%) drugs, while in MEDLINE name and address of manufacturers was not mentioned (Table 1).

Out of all the drug information sources, maximum number of brand names and generic names were seen in Medicinal Strips/Package Inserts, followed by Wikipedia. Maximum pharmacological data was seen in Martindale and least in Drug Today. Regarding drug information, maximum information was given by Formulary and least by Drug Today. Maximum data regarding pharmaceutical information and legal information was given in Medicinal Strips/Package Inserts, while least was given in Drug Today and MEDLINE each. Overall, no source contained complete information as per WHO standards and complete drug information (Table 1).

On comparing the information provided by different sources, it was found that information regarding maximum number of drug names and legal aspects was given by Medicinal Strips/Package Inserts, pharmacological data by Martindale, clinical information and pharmaceutical information by National Formulary of India.

When all parameters were compared and evaluated, the maximum information was provided by Formulary (2467), followed by Medicinal Strips/Package Inserts (2127), Martindale (1924), Wikipedia (1680), MEDLINE (1550) and Drug Today (537) (Table 1).

While evaluating the adequacy of drug information by different sources used by patients and healthcare providers, as per WHO, none of the source showed complete adequate information. Inadequate information for maximum number of drugs was given by MEDLINE, followed by Drug Today, Medicinal Strips/Package Inserts, Wikipedia, National Formulary of India and Martindal. In overall comparison, Martindale had most number of drugs with partially adequate data (218; 64.12%), followed by National Formulary of India (167; 49.1%) and Medicinal strips/Package inserts (108; 31.7%). All the drug information sources studied, including the standard drug information source *i.e.*, the National Formulary of India, provided somewhat incomplete and inadequate drug information commonly used by patients and healthcare providers (Table 2).

## DISCUSSION

The drug information is complex, voluminous, heterogenous and dynamic. Multiple sources of drug information are there but there is no single source of drug information still available to provide appropriate scientific, evidence-based, complete information. Therefore, the healthcare providers usually remain in dilemma while referring the source of drug information. This situation is further compounded by the omnipresence of internet and its impact on health education and the ways healthcare provider assess information for updating and learning.

The present scenario is completely different from the earlier drug information sources where the prescriber had to depend solely on national formularies. The national formularies, though written originally in Latin, saw changes in succeeding years till Second World War in 1939 when formularies were prepared for wartime use. Now presently even British National Formulary is being revised every year twice since March 2012 [14].

The Indian National Formulary started its first edition in the year 1960 and has been providing information to the healthcare providers since then and latest version has been introduced in the year 2016.

In the present day, the health professional requires a digest based on evidence and best practice on which to frame their discussions and treatment at a point of care. Therefore, depending on this the role of modern formulary has become collecting, filing, filtering and publishing guidance in an appropriate manner. In addition, the well circulated formulary can contribute to the purpose and intent through a chain of professionals from prescribing to pharmacy and from dispensing to team charged with administering medicines and their effects. This could be achieved by commissioning research to monitor the extent to which it meets these requirements without bias.

With open access to the internet, Wikipedia has assumed a front runner role in providing drugs information. Pharmacists, pharmacology students, doctors, medical students and other drug information seekers continuously refer Wikipedia online. It has been reported that the Wikipedia rates amongst first ten drug based web searches [15].

However, number of studies have examined the accuracy and completion of health and drug information in Wikipedia and found variable results and some found information often incomplete. Parallel to Wikipedia, another advanced search site from the network of MEDLINE website is frequently assessed for providing comprehensive information regarding drugs. MEDLINE has become one of the most visited website. The medical providers in countries where adequate internet facilities are lacking (under developed countries),

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students/healthcare providers need to update their textbook knowledge continuously and master the skills in patient care, have to depend on periodically published drug information from MIMS, CIMS, Drug Today due to flooding of newer drugs in the market.

Since the research and results are equivocal in recommending completeness of the drug information from the different sources, therefore, the present study was conducted to analyze and validate commonly used medical information sources with respect to WHO Essential Medical List. The sources selected for the validation in the current study were based on the preliminary survey collected by the investigators to verify the most commonly used drug information sources for accessing drug information among the healthcare providers and patients.

In this context to Wikipedia, Medicinal Strips/Package Inserts, MEDLINE, Martindale and Drug Today were observed to be the most commonly referred in seeking medicine information by the local healthcare providers and patients. These were analyzed in the current study for completeness, adequacy of drug information sources. The National Formulary of India was taken as standard source of information and all selected sources were compared with it.

The results of the current study show that variations exist among various patient used sources as well as the commonly used sources by healthcare providers. None of these sources in our study provided complete and adequate drug information which is very serious concern. Regarding Wikipedia, it largely stressed upon brand and generic names, indications, adverse drug reactions, dosage form and route of drug administration. Medicinal Strips/Package Inserts also stressed on the brand name, indications, dosage form, overdose treatment description of the product and package. Whereas, MEDLINE largely stressed upon the generic name, indications, precaution and warnings, adverse drug reactions, overdose treatment, dosage form and route of drug administration. Unlike this, Martindale stressed more on generic name, mechanism of action, pharmacokinetic data, indications, special situations, contraindications, precautions and warnings, adverse drug reactions, dosage form and route of drug administration. While the Drug Today largely stressed on generic and brand names, indications, pharmacokinetic data, adverse drug reactions, overdosage treatment and description of product and package. The National Formulary of India in our study stressed on providing information on indications, dosage, dose interval, contraindications, precautions/warnings, adverse drug reactions, route of drug administration, dosage form and storage. Besides this, it was only the National Formulary of India which provided information regarding the regulatory schedule of the drug and risk category for pregnancy and lactation.

In the current study we observed that Martindale provided scientifically-based information regarding pharmacological data, clinical information, pharmaceutical information relatively better than all other sources studied which included Wikipedia, Medicinal Strips/Package Inserts, MEDLINE, Drug Today except National Formulary of India. Although, overall even Martindale and National Formulary of India failed to provide complete and adequate drug information. Although comparing with all the studied drug information sources, National Formulary of India appeared to be the best source of drug information, but still it failed to provide complete and adequate information as per the criteria laid down by World Health Organization. Similar results were endorsed by Gitanjali, wherein the author addressed similar issues of inadequate information given by National Formulary of India [16].

The possible constraints in providing complete domains of drug information as prescribed by WHO may have been the fact that such document needs to be compiled in a compact way so that it can be very easily carried by physicians in their pockets during their clinical bedside visits. However, in view of providing inadequate and incomplete information, it is highly recommended that complete drug information with evidence and references be provided as per the recommended WHO format and the same can be made accessible to all the physicians and prescribers in smart mobile compatible version which shall serve the purpose meaningfully beside being clinically relevant.

The results of the current study largely recommend that all these drug information sources need to be updated and made complete as per the WHO recommendations so that whosoever access these sources, whether patients or healthcare providers, they get complete, scientific and evidence-based drug information.

It is even more important to make these sources complete and updated because otherwise this shall encourage the tendency of the healthcare providers to rely upon various direct to physicians marketing literature/sources of drug information in the form of medicine leaflets, pamphlets, booklets, journals and teaching material which are likely to provide incomplete, biased, inaccurate, exaggerated, ambiguous or over-simplified information as pointed out by various studies [17,18,19,20,21].

Further, the information provided by market sales representatives lacks balance information with great emphasis on the benefits of the product and less information about potential risks about the medication. Also, many a time such sources fail to mention side effects, dose interval, toxicity information of the related products.

## LIMITATIONS OF THE STUDY
1. It is a descriptive study.
2. No attempt has been made to see the impact of various sources of drug information on prescribing behavior of doctors and patients.
3. No attempt has been made to study the quality of drug information provided by these sources.

## CONCLUSION
The current study highlights that sources of drug information likely to be used by patients (Wikipedia, Medicinal strips/Package inserts) and healthcare providers (Drug Today/Martindale/MEDLINE) failed to provide complete and adequate drug information. In comparison to National Formulary of India, all these sources significantly provided more inadequate information. National Formulary of India also failed to provide complete/adequate information as per the standards laid down by WHO. Further, these sources significantly varied in providing the drug information. Relatively National Formulary of India, followed by Martindale emerged as better among the all. The current study strongly recommends that all these sources need scientific upgradation, otherwise in the present state it can have negative impact on the drug information seeker.

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