SURVEY ANALYSIS

STUDY OF WHO PRESCRIBING INDICATORS IN OUTPATIENT PHARMACIES OF GANDHINAGAR, GUJARAT

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ABSTRACT

Using WHO-INURD prescribing indicators attempt has been made to quantify and justify the concern of poor prescribing quality in outpatient pharmacies of Gandhinagar, Gujarat. A prospective observational study was commenced and 501 prescriptions were enrolled in 6 months of study periods from 3 outpatient pharmacies. As a result majority of WHO-INRUD prescribing indicators were deviating from standard limits, showing site wise variability. WHO-INRUD prescribing indicators : Average number of drugs per encounter, Percentage of drugs prescribed by generic name, percentage of encounters with an antibiotic prescribed, percentage of encounters with an injection prescribed, percentage of drugs prescribed from essential drugs list were found 3.01, 1.45%, 22.5%, 2.25%, 44.27% respectively. Numbers Sure does indicate several indicators within limit but major site wise variation and presence of influencing factors cannot be denied. Great matter of concern towards poor prescribing and high trend of medication error requires in depth assessment with consideration of influencing factors and its pattern in such area of interest.

KEY WORDS

WHO, Drug use indicators, Prescribing indicators, Physician's Practice Patterns

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INTRODUCTION

Since the early ages providing quality healthcare has remained at prime concern. As arising pharmacoepidemiological & pharmacoeconomical concerns provoked evolution of healthcare in numbers & monetary units, prime concern of providing safe and quality health care has been found in circle of doubts. Sensing such issue incorporation of modern tools and methods were considered necessary to evaluate quality of healthcare in every aspect. So many factors of modern healthcare system gave birth to alarming problems of inappropriate drug use and medication errors. Medication errors affect 1.5 million people in the United States each year, resulting in additional $3.5 billion in extra medical costs. So, let's not talk about Indian setup because it would be much higher than expected [1]. Gradually it was made clear that for providing quality in healthcare appropriate use of drug is vital [2]. It is not hard to find literature addressing problem of medication error. It was no more in doubt that irrational use of medicine is serious threat worldwide [3]. But what we lack are methods to manage problem of medication error effectively. Although there are plenty available but there is always a room for bigger and better. Being essential part of healthcare system, drugs are increasing constantly with limited financial resource [4]. Not only it is leading cause of adverse drug reactions worldwide but also puppeteer of increased morbidity and mortality rates, wasted resources, unwanted cost and cause for antibiotic resistance [5-6]. Rise in such trends are also noticed with rise in expectations and standards of healthcare. Focusing on an integral part of healthcare, 'prescriptions' are not the only mean of communication between healthcare providers but also provides statement on quality of healthcare via means of details of drug prescribed. Considering prescriptions as 'crude' to extract vast variety of data can be extracted to fulfill the need of safe and effective drug use. However, assessing the quality of diagnosis and evaluating the adequacy of drug choices is a complex undertaking in practice, and beyond the scope of any evaluation method.

Since the time when Indian health care received modern touch irrational use of drug and medication error has been a leading and alarming problem [1, 3, 7, 8]. Sensing the situation research has been done with the intention of identifying the triggers and preventive measures. But situation doesn't seem to have improved. Even if we consider the lack of man power, lack of resources and quality of education in olden days, which would have caused such devastating results the present status is no better. In fact it is more devastating. The rates of medication error have doubled with course of time compared to early results[9,10].With increasing demand of improving drug use, in 1985 major conference at Nairobi for rationale use of drug was held by WHO. Initially with lack of homogenous agreement Indicators were field tested in Yemen & Uganda. With this framework, INRUD jointly made contribution in systemic way to develop modified core indicators, which were again tested in Sudan, Uganda, Nigeria, and Tanzania [11]. However, assessing the quality of diagnosis and evaluating the adequacy of drug choices is a complex undertaking in practice, and beyond the scope of the core indicators. Still advantages of core indicators are later follow-up of health problem-specific or drug-specific analyses can be carried out on the same data. Giving not only the insight of practice but also provides trail to explore advanced and detail study of drug utilization and behavior of drugs. All five prescribing indicators dose address unique field of practice separately. As average number of drugs per encounter measures the degree of Polypharmacy, Percentage of drugs prescribed by generic name to measure the tendency to prescribe by generic name having its own advantages. And so on percentage of encounters with an antibiotic prescribed assess the degree and pattern of antibiotics use in setup, Percentage of encounters with an injection prescribed measure the overall level of use of important, but commonly overused and costly form of drug therapy. Most importantly percentage of drugs prescribed from essential drugs list or formulary measure the degree to which practice conforms to a national drug policy, which ultimately justifies safe, effective and rational use of drug along with cost effectiveness [11]. Answers are made clear with reasons like lack of skilled prescribers, lack of standards in prescribing, poor communication among healthcare providers, lack of education among patients and strong marketing strategies by drug manufacturers. [13, 14, 15, 16] If we talk about drug use indicators by WHO-INRUD , Literature clearly Indicates results are well within limits and rational practice have been observed throughout African region [18-21], Gulf countries [22,23], East Asian countries [24-26] and American Continents [27]. At the other hand Indian literatures throughout the years clearly indicates deviation in almost every indicator and irrational drug use regardless of condition and setup [12,28-34]. What is it, which makes us so different than well-developed health care settings and causes such results? No doubts, we are leading in economical capital and consumer capital in healthcare among world's finest, but why we cannot capitalize in quality of care. Thus, we have made attempt to assess current setting and to justify such reasons in our study.

MATERIALS AND METHOD

A prospective observational study was carried out in 3 outpatient pharmacies of Gandhinagar, Gujarat for six months from October 2015 to March 2016. During this period 501 prescriptions were enrolled in study. Data was collected at random times during the study by assigned data collector. Data was collected in pre-designed data collection form during process of dispensing. From collected data WHO prescribing Indicators were calculated according to the guidelines. Among them for calculating percentage of drugs from Essential Medication List, WHO list of essential medication was taken into consideration. Approval from K. B. Independent Ethics Committee (ECR/144/Indt/GJ/2014) was taken for protocol: KBIEC / 2015 / 61 to conduct the study in October 2015.

The inclusion criteria included prescriptions of patients having age above 18 years, regardless of gender. And the exclusion criteria were (1) Prescriptions, written on scraps of paper, not containing information about either prescriber or patient (3) Pregnant women were excluded. (4) Repeat and refills were not taken in to consideration.

WHO-INRUD Prescribing Indicators [11]:

The indicators of prescribing practices measure the performance of health care providers in several key dimensions related to the appropriate use of drugs. The indicators are based on the practices observed in a sample of clinical encounters taking place at outpatient health facilities for the treatment of acute or chronic illness. They can be observed retrospectively or prospectively, the core prescribing indicators do not require the collection of any information on signs and symptoms. Because the samples of clinical encounters covers a broad spectrum of health problems, the core prescribing indicators measure general prescribing tendencies within a given setting, independent of specific diagnoses. However, determining the quality of diagnosis and evaluating the adequacy of drug choices is a complex undertaking in practice, and beyond the scope of the core indicators. The advantages of the details are that later follow-up health problem-specific or drug-specific analyses can be carried out on the same data. Neither drug use indicators are gold standard to assess quality nor is the standardized technique available to assess quality of prescribing. The drug use indicators are best understood as first line measures and used to guide further action and to guide subsequent action.

1. Average number of drugs per prescription:
Aim: To measure the degree of Polypharmacy.
Method: Average, Total number of drugs is divided by number of prescription.
Prerequisites: Combination drugs are counted as one. Guidelines are needed on how to count certain ambiguous prescribing practices.

2. Percentage of drugs prescribed by generic name:
Aim: To measure the tendency of prescribing by generic name.
Method: Percentage, calculated by dividing the number of drugs prescribed by generic name by the total number of drugs prescribed, multiplied by 100.
Prerequisites: Manual skills required to identify generic names and brand names.

3. Percentage of encounters with an antibiotic prescribed:
Aim: To assess the degree and pattern of antibiotics use in setup.
Method: Percentage, calculated by dividing the number of antibiotics prescribed by the total number of drugs prescribed, multiplied by 100.
Prerequisites : The indicators of antibiotic use are quite sensitive to whether or not certain groups of drugs are included as antibiotics, Another issue in the definition of antibiotics for drug use indicators is whether topical antibiotic preparations, such as skin creams and ophthalmic ointments, should be counted as antibiotics or not.

4. Percentage of encounters with an injection prescribed:
Aim: To measure the overall level of use of important, but commonly overused and costly form of drug therapy.
Method: Percentages, calculated by dividing the number of patient encounters during which an injection are prescribed, by the total number of encounters surveyed, multiplied by 100.
Prerequisites: Investigators must be instructed about which immunizations are not to be counted as injections.

5. Percentage of drugs prescribed from essential drugs list or formulary:
Aim: To measure the degree to which practices conform to a national drug policy, as indicated by prescribing from the national essential drugs list.
Method: Percentage, calculated by dividing the number of products prescribed which are listed on the essential drugs list or local formulary (or which are

equivalent to drugs on the list) by the total number of products prescribed, multiplied by 100.

Prerequisites: Copies of a published national essential drugs list are needed. Procedures are needed for determining whether or not brand name products are equivalent to ones appearing in generic form on the drug list.

RESULT

At the end of study, from 3 outpatient pharmacies 501 prescriptions were enrolled among which 257 (51.29 %) were of male and 244 (48.70 %) were of female (Table 1).

TABLE 1: GENDER WISE DISTRIBUTION OF PRESCRIPTIONS

Gender	Numbers (N)	Percentages (%)
Male	257	51.29%
Female	244	48.70%
Total	501	100%

Total 1511 drugs were prescribed. Average number of drugs per encounter, % of drugs prescribed by generic name, % of encounters with an antibiotic prescribed, % of encounters with an injection prescribed, % of drugs prescribed from essential drugs list were 3.01, 1.45%, 22.5%, 2.25%, 44.27% respectively (Table 2).

TABLE 2: WHO-INRUD PRESCRIBING INDICATORS

WHO Prescribing Indicators	Standard Value	Observed Value
Average Number Of Drug Prescribed Per Prescription	< or = 3	3.01
Percentage Drugs Prescribed By Generic Name	100%	1.45 %
Percentage Drugs Prescribed From Essential Medication List	100 %	44.27 %
Percentage Antibiotics Prescribed	< or = 30 %	22.5 %
Percentage Injectable Prescribed	< or = 10 %	2.25 %

Relationships between area characteristics and prescribing patterns are well accepted and described now. [31] Thus, Site wise assessment was also done to evaluate variability in results and with no wonder remarkable variability was seen (Table 3).

TABLE 3: WHO-INRUD PRESCRIBING INDICATORS (SITE WISE)

WHO Prescribing Indicators	Site - 1	Site - 2	Site - 3
Average Number Of Drug Prescribed Per Prescription	4	2.98	2.97
Percentage Drugs Prescribed By Generic Name	0%	0.27%	5.50%
Percentage Drugs Prescribed From Essential Medication List	59.72%	45.42%	37.39%
Percentage Antibiotics Prescribed	25%	24.40%	15.94%
Percentage Injectable Prescribed	16.66%	1.27%	2.31%

As a part of secondary objective prescribing pattern was also assessed with observation of Antibiotics leading the charts with 22.50%. (Table 4)

TABLE 4: PRESCRIBING PATTERN ACCORDING TO CLASS OF DRUGS.

Class Of Medication	Percentage (%)
Antibiotics	22.50 %
Antihistamines	10.72 %
Analgesics	8.47 %
Vitamins and Supplements	5.22 %
Proton Pump Inhibitors	4.23 %
Beta-2 adrenergic agonists	2.97 %
H2 Receptor antagonists	1.52 %
Xanthine Derivatives	1.25 %
5 HT3 receptor antagonists	1.19 %
Other	43.21 %

Percentages calculated from total number of drugs prescribed (N=1511)

Seasonal, Environmental and Geographical factors can be predicted as precedes of results. Class like macrolides and penicillin were seen in highest amount among antibiotics prescribes with 32.35% and 9.70% respectively. Trend of combination was also noticed high with penicillin and beta lactamase leading the charts by 28.52%. Overuse of antibiotics, particularly broad-spectrum antibiotics, in primary care is a major contributing factor to reduced drug efficacy, increased prevalence of resistant pathogens in the community, and the appearance of new co-infections. Report of antibiotics prescribed here is not an illustration with regards of WHO prescribing indicators. It only gives explanation of prescribing pattern of antibiotic drugs. Fact should be kept in mind that WHO considers selected class of drug to be counted as antibiotics which is illustrated by WHO in Model list of essential medication. (Table 5)

TABLE 5: PRESCRIBING PATTERN OF ANTIBIOTICS (TOTAL N=340)

Class Of Antibiotic	Number (N)	Percentage (%)
Macrolides	**110**	**7.27%**
Azithromycin	110	7.27%
Penicillin + Beta lactamase	**99**	**6.55%**
Amoxicillin + Clavulinic acid	97	6.41
Penicillin +Cephalosporin	1	0.06%
Cloxacillin + Cefixime	1	0.06%
Penicillin	**33**	**2.18%**
Amoxicillin	15	0.99%
Amoxicillin + Cloxacillin	17	1.12%
Ampicillin + Cloxacillin	1	0.06%
Cephalosporins	**31**	**2.05%**
Cefpodoxime	5	0.33%
Ceftriaxone	4	0.26%
Cefadroxil	12	0.79%
Cephalexin	1	0.06%
Cefixime	9	0.59%
Floroquinolones	**21**	**1.38%**
Ofloxacin	3	0.19%
Moxifloxacin	5	0.33%
Levofloxacin	7	0.46%
Nadifloxacin	1	0.06%
Sparfloxacin	5	0.33%
Floroquinolones + nitroimidazoles	**13**	**0.86%**
Ofloxacin + Ornidazole	13	0.86%

Nitroimidazoles	**8**	**0.52%**
Itraconazole	1	0.06%
Fluconazole	1	0.06%
Clotrimazole	4	0.26%
Metronidazole	2	0.13%
Aminoglycoside	**5**	**0.33%**
Amikacin	4	0.26%
Tobramycin	1	0.06%
Allylamines	**5**	**0.33%**
Terbinafine	5	0.33%
Benzimidazole	**4**	**0.26%**
Mebendazole	4	0.26%
Cephalosporins + Beta lactamase	**4**	**0.26%**
Cefixime + Clavulinic Acid	1	0.06%
Cefpodoxime + Clavulinic acid	1	0.06%
cefoperazone + Salbactum	2	0.13%
Other	**7**	**2.33%**

Detailed illustration of antibiotics. Percentages are calculated from total number of drugs prescribed (N=1511) to get insight of degree of prescribing.

Apart from antibiotics other classes of drugs are also important with respect to assess prescribing pattern and to get on any inference. It does not only help to assess economic and epidemiological aspects but also states nature of prescribing. Consumption of Antihistamines, Analgesics and Proton pump inhibitors were seen highest with 10.72%, 8.47%, 4.23%. Among analgesics NSAIDS were seen highest in trend. With surprise numbers of vitamins supplements prescribed was seen high 5.02% compared to other studies done. (Table 6)

TABLE 6: PRESCRIBING PATTERN OF OTHER CLASS OF DRUGS

Class Of Drug	Number (N)	Percentage (%)
Antihistamines	**162**	**10.72%**
Citrizine	110	7.27%
Levo Citrizine	52	3.44%
Analgesics	**128**	**8.47%**
Aceclofenac	10	0.66%
Diclofenac	36	2.38%
Etodolac	1	0.06%
Ibuprofen	22	1.45%
Mefanamic Acid	10	0.66%
Nimesulide	33	2.18%
Tramadol	16	1.05%
Vitamins	**76**	**5.02%**
Protein Supplements	**3**	**0.19%**
Proton Pump Inhibitor	**64**	**4.23%**
Pantoprazole	11	0.72%
Rabeprazole	31	2.05%
Omeprazole	19	1.25%
Esomeprazole	3	0.19%
Beta 2 Adrenergic Agonist	**45**	**2.97%**
Salbutamol	7	0.46%
Levosalbutamol	30	1.98%
Terbutaline	8	0.52%
H2 Receptor Antagonist	**23**	**1.52%**

Famotidine	5	0.33%
Ranitidine	18	1.19%
Xanthine Derivatives	**19**	**1.25%**
Theophylline	3	0.19%
Doxofylline	16	1.05%
5HT3 Receptor Antagonist	**18**	**1.19%**
Ondansetron	18	1.19%
Leukotrienes Receptor Inhibitor	**13**	**0.86%**
Montelukast	13	0.86%
Other	**620**	**41.03%**

Detailed illustration of drugs other than antibiotics. Percentages are calculated from total number of drugs prescribed (N=1511) to get insight of degree of prescribing.

DISCUSSION

It is made clear that this study have several limitations which makes difficult to justify anything precisely. In spite majority of Indicators being in limit high variability was seen site wise, yet as part of supporting evidences, literature sure dose indicate irrational drug use. Leaving In general Discussion apart If we focus on WHO-INURD prescribing Indicators Polypharmacy is a very common problem in current with which Indian Health care system is dealing with , As a part of less effective factors high Prevalence of co-morbidities and poor record maintenance of Indian health care system can be considered.

Very less percentages of drugs prescribed by generic name is not only matter of concern due to irrational prescribing but it also have drawbacks like increased chances of medication error, Interactions and Increased cost burden. EML \ EDL varies according to nation or authority due to geographical and other factors. More number of drugs from EML indicates rational and cost-effective prescribing. Use of essential drugs offers many advantages including cost, safety, and effectiveness. Overuse of antibiotics is not only concern of cost but it is main cause of development of antibiotic resistance, ADR and Interactions. It will not only increase the cost but suffering is also followed by it [36, 38]. Moreover it is more or less involved with irrational use of drugs. Here results may not indicate overuse of antibiotics because personal factors may influence and even rationality of antibiotic prescription is not checked so it is difficult to come at any inference. But still published literatures leave no doubts about irrational antibiotic prescribing moreover prescribing pattern of antibiotics as per literatures are also matching with cultivated results [39] which may be due to:

- Misuse of Antibiotics by the Public [35]
- Poor knowledge of patients about antibiotics [36]

As a part of core indicator percentage of injectable medicines prescribed also poses great value. Degree of injectable medicine use dictates perception of patients and health care providers, Although Injections are costly and painful it indicates higher burden on patient's pocket moreover prescribing injection-delivered medications can produce side effects and infections [38]. In spite of this indicator being in limits trend of irrational injectable use has been observed in recent times which may prove dangerous by spreading infections by mean of its kind. Recent trend may due to: Patient insisting for injection and expecting quick relief.

Several reasons are seen very common as a cause in every prescribing indicators. Which are [40]:

- Absence of Standard prescribing guidelines.
- Lack of skill and knowledge in health care professionals.
- Marketing strategies of drug manufacturing companies.
- Lack of regulatory authority influence and guidelines.
- Lack of education in patients. [37]

Apart from it for all indicators influence of pharmaceutical firm enticements on physician prescribing patterns cannot be denied [41] .So it is very obvious that focusing and improvement in such areas can at least cause improvement in results. Several advisable steps to improve prescribing practice are [30, 35, 42, 43]:

- CME \ CPD can contribute to improve skill and knowledge of health care providers.
- Strict regulatory influence.

- Establishment of standard guidelines to practice.

Limitations:

- Although it is not required but due to lack of manpower and setup we couldn't manage to cultivate precise information on age, disease condition and other demographics which could have been helpful to justify rationality of drug use.
- We couldn't manage to evaluate rationality of prescription due to lack of information and follow up.
- Variability such as environmental factors and Seasonal factors were not taken into consideration.
- Standard for duration of valid prescription is not taken in to consideration (E.g.: Old prescription to be considered or not).

Trend of polypharmacy, Very less prescribing of generic drug and essential medication is seen very common. Although results cannot announce any precise statement on rationality and pattern of drug use but it sure dose indicate that such situations need to be addressed and managed adequately. CME \ CPD to improve skill and knowledge of health care providers along with strict regulatory influence and standard guidelines to practice pharmacist oriented collaborative approach can be a key in management of medication error [17]. Medication error is high in current practice setting and more modern and handy

techniques are required to continuously monitor practice precisely to suit the Indian setup.

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AUTHOR CONTRIBUTION

All authors have made equal substantial contributions to conception and design, acquisition of data, analysis and interpretation of data with intention to fulfill academic requirement. All authors have been involved in drafting the manuscript content and have read and approved the final manuscript.

CONFLICT OF INTREST:

All authors of this research paper have directly participated in the planning, execution, or analysis of this study and approved the final version submitted; There are no directly related manuscripts or abstracts, published or unpublished, by any authors of this paper; Our Institute's (K.B.INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH) representative is fully aware of this submission. Neither our project was sponsored nor we have conflicts of interest to declare.

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ABBREVIATIONS:

WHO - World Health Organization

INRUD - International Network of Rational Use of Drugs

EDL - Essential Drug List

EML - Essential Medication List

ADR - Adverse Drug Reaction

CME - Continuous Medical Education

CPD - Continuous Professional Development