



## FIXED DOSE COMBINATION: UNDERSTANDING OF IMMINENT PHARMACIST

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### ABSTRACT

This study was conducted to evaluate the awareness of pharmacy students' about prescribing fixed dose combination (FDC) in pharmacy institutions in Karachi. A cross sectional study was conducted during July-Sep, 2013. Participants' overall response towards the importance of the FDCs was found positive. Out of 600 students, 511 pharmacy students (85.16%) responded the questionnaire, belonging to public and private institutes of Karachi. 47.7% of the respondents were aware of the practice for prescribing FDCs. Only 29.15% students were informed about the standard protocol for prescribing FDCs. 65.75% of the students agreed that patient compliance can be improved by using simpler dosage schedule of FDCs. On the other hand 49.9% of the students claimed that FDCs may lead to alteration of therapeutic effect due to possible drug-drug interaction. It is concluded that pharmacy students' awareness of prescribing FDC is the demand of modern medicine to improve the patient compliance, ease in drug administration, safe and successful use of drugs.

**Key words:** Fixed dose combinations, pharmacy students, Pakistan

### INTRODUCTION

The term Fixed Dose (drug) Combination is defined as "a combination of two or more pharmacologically active compounds formulated as a single medicine irrespective of dosage form designed." According to FDA; it is a combination of drug with another drug or a device or a biological product use for treatment.<sup>[1,2,3,4]</sup> There are certain factors that contribute in the rationality of FDCs such as mechanism of drugs action; pharmacokinetics of drugs and toxicological study of drugs in combination. Rational drug therapy focuses on safety, effectiveness and good quality of drug to be used for treatment purpose.<sup>[4, 5]</sup>

These combinations may range from simple nutritional tonics i.e. multivitamins to infectious diseases such as HIV/AIDS, malaria, tuberculosis etc.<sup>[1]</sup> Moreover FDCs are also used in various ailments such as orthopedic disorders, aches, cough, GI infections, diarrhea, anemia etc.<sup>[6]</sup> For the treatment of diseases like antiretroviral, antitubercular, antimalarial and anticancer therapy, FDCs play an important role in improving the patient's quality of life.<sup>[4,7,8]</sup>

WHO also favored this pattern of drug use and in 14<sup>th</sup> model list of essential drugs, three hundred and twelve formulations were included containing eighteen formulations in the form of FDC.<sup>[9,10]</sup> Reasons to use FDC include availability of an easy combination, ease of prescribing by physician,<sup>[4]</sup> patient adherence i.e. reduced pill burden on patient etc.<sup>[11]</sup>

However most FDCs bear the disadvantage of increased adverse effects, drug-drug interactions, needless financial burden,<sup>[12]</sup> increase hospitalization, decreased quality of life and some times increased medication cost.<sup>[4]</sup> Dose adjustment of combined drugs, their frequency of drug administration is also complicated if both drugs in combination have different pharmacokinetics.<sup>[13]</sup> Therefore it is suggested that clinical testing of such combination drugs should be conducted to avoid any complication and irrational therapy to ensure patient safety.<sup>[14,15]</sup> There are numerous FDCs which are available in the market and hence the knowledge regarding the prescribing patterns is important for

better health outcomes of community. Pharmacists are believed to be the drug expert; therefore there is a need to evaluate the awareness of pharmacy students towards the fixed dose combinations in order to promote the rational drug therapy in future.

## MATERIAL AND METHOD

This cross sectional study was conducted during July-Sep 2013 in one public sector and three private institute of Karachi, to determine the students' awareness about prescribing Fixed Dose Combination. In this study the target population was 4<sup>th</sup> and 5<sup>th</sup> year pharmacy students only. For this purpose a Questionnaire comprising of 2 sections was administered among students. The first section of the study comprised of socio-demographic data of the participants and second section contained a total of 15 questions related to evaluate awareness of students about FDCs. Furthermore verbal informed consent was taken from the participants of this study. For data analysis Statistical Package for Social Sciences (SPSS 20.0) was used to interpret the response of students.

## RESULT & DISCUSSION

The present study comprises of five hundred and eleven students of fourth and final year Pharm-D, belonging to one public sector and three private sector institutes of Karachi, after taking their consent. The demographic data is recorded in Table 1. Only 11.35% of the students were male. 32.68 % of the participants belonged to the public sector while 67.31% of the respondents were enrolled in private institutes. 47.74% of the participants were fourth year whereas 52.25% were final year pharmacy undergraduates students.

Responses to the questionnaire items exploring the awareness of pharmacy students about prescribing fixed dose combinations are recorded in Table 2. 47.7% of the respondents were aware of the practice for prescribing FDCs. Only 29.15% of the students were informed about the standard protocol for prescribing FDCs. 65.75% of the students agreed that patient compliance can be improved by using simpler dosage schedule of FDCs. 53.03% of the students agreed that FDCs helps to minimize the chances of

adverse drug reaction. 49.9% respondents favored that FDCs are helpful to reduce inadvertent medication errors. 51.85% of the students agreed that potential of drug abuse can be minimized by using FDCs.

On the other hand 49.9% of the students claimed that FDCs may lead to alteration of therapeutic effect due to possible drug-drug interaction. Responses of the students about the source of information for FDCs are explored in Fig.1. Internet (19.17%), Essential drug list (15.26%) and textbook (10.95%) were considered as the reliable sources of information for FDCs by the students. Statistically significant difference was analyzed between the response of fourth and final year pharmacy under graduates and found to be significant [p-value < 0.0001].

It is observed that trend of prescribing fixed-dose combinations, varies from country to country. In Japan, only 10 percent of the new products were FDCs, whereas, in European countries like Spain, it was up to 56 percent. [4] Pakistan is under developed country. Rational combinations can be of immense help to the health care system to improve patient's quality of life. In the presented study a large number of pharmacy students was aware of the practice for prescribing FDCs. But still there is a need to educate pharmacy students about the standard protocol of prescribing FDC to minimize irrational drug use.

## CONCLUSION

Development of fixed-dose combinations is becoming increasingly important from public health perspective. More than one-third of all the new drug products introduced worldwide during the last decade were FDC preparations. It is suggested that clinical trials of such drugs should be conducted to avoid hazards associated with these combination drugs.

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## CONFLICT OF INTEREST

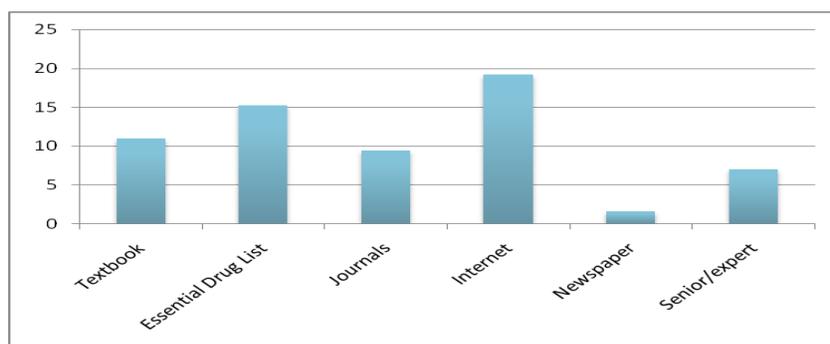
Authors have no conflict of interest.

**Table I Characteristics of the study population**

S.No	Characteristics	Number (Percentages)
1	<b>Gender</b>	
	Male	58 (11.35)
	Female	453 (88.64)
2	<b>Institution</b>	
	Public sector	167 (32.68)
	Private	344 (67.31)
3	<b>Year of study</b>	
	Fourth year	244(47.74)
	Final year	267(52.25)

**Table II Pharmacy students' knowledge about fixed dose combinations**

S.No	Knowledge	Yes	No	Don't know
1	Ever observed Fixed dose combinations ( FDCs) in prescription	244(47.74)	159(31.11)	108(21.13)
2	Knowledge about Standard protocol for FDCs prescribing	149(29.15)	223(43.63)	139(27.20)
3	Patient compliance can be improved by using simpler dosage schedule of FDCs	336(65.75)	69(13.50)	106(20.74)
4	FDCs helps to minimize the chances of adverse drug reaction	271(53.03)	137(26.81)	103(20.15)
5	FDCs are helpful to reduce inadvertent medication errors	255(49.90)	95(18.59)	161(31.50)
6	Effect of FDCs are same as that of synergistic combinations	183(35.81)	156(30.52)	172(33.65)
7	Knowledge about the single expiry date of FDCs	178(34.83)	127(24.85)	206(40.31)
8	FDCs are expensive than synergistic medicines	179(35.02)	188(36.79)	144(28.18)
9	FDCs have less side effects than individual drugs	234(45.79)	137(26.81)	140(27.39)
10	Potential of drug abuse can be minimized by using FDCs	265(51.85)	97(18.98)	149(29.15)
11	FDCs dosing is inflexible and cannot be regulated according to patients' needs	197(38.55)	153(29.94)	161(31.50)
12	Some FDCs having incompatible pharmacokinetics are irrational	231(45.20)	88(17.22)	192(37.57)
13	Drug-drug interaction in FDCs may alter therapeutic outcomes	255(49.90)	93(18.19)	163(31.89)
14	Knowledge about any FDCs that has been banned	69(13.50)	183(35.81)	259(50.68)

**Fig. I Source of information for FDCs**

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