#### **RESEARCH ARTICLE**



# Time to teach basic and regulatory aspects of art of prescription writing for better doctor-patient safety and keeping communication accessible and straight

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#### Abstract

**Purpose** The basic and regulatory knowledge of prescription writing is essential for every medical student to evolve into a prescribing physician. Prescription becomes the most important clinical pharmacology tool and evidence of the medication access, prescription errors, prescribing errors, negligence and further litigations once released from the hands of the physicians. A questionnaire based cross-sectional survey was done to evaluate knowledge of basic and regulatory aspects of prescription writing in the light of growing violence against physicians in India.

**Methods** The basic and regulatory knowledge and awareness of 90 practicing physicians was evaluated for arts of prescription writing by a novel questionnaire based on Indian regulatory guidelines. It was assessed for content validity, face validity, readability and reliability. A statistical significant Cronbach's alpha values of greater than 0.9, Flesh Reading Ease score of 37.4 and Flesch-Kincaid Grade level of 11.2 were obtained. A total of 39 questions comprised of 70 statements categorised into three broad sections containing 13 questions in each were asked in 30 min.

Results The knowledge of the prescription writing is very limited in doctors. They are not sure that Over-The-Counter drugs do not need prescription, pharmacist is the decoder of their written prescription, cross-prescribing (prescribing drugs of other system of medicine) is illegal and they should not dictate prescription on phone. Majority of the physicians are unaware that writing prescription serial number, Rx, refill information and dispensing direction of habit forming drugs is not legal requirement in India.

**Conclusion** Medication access through prescription writing is marred with prescription errors. The physicians have limited regulatory and basic knowledge of prescription writing. Therefore their training of prescription writing through defined global teaching modules is needed. The prescription communications need to be lucid, accessible, comprehensive and straight between doctors and patients following the tenets of country specific regulatory requirements.

**Keywords** Prescription writing · Clinical pharmacology · Medication access · Basic and regulatory prescription elements · General practice

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## Introduction

The National Health Services in United Kingdom have estimated that prescribing is the most common therapeutic approach offered to the patients in general practice healthcare [1]. The handwritten paper prescription is still the main mode of communication between the physicians, pharmacists and the patients in most countries [2]. It consists of a decision making process called prescribing and another part that involves writing is known as prescription [3]. A prescription is defined as "a written order, which includes detailed instructions of what medicine should be given to whom, in what formulation and dose, by what route, when, how frequently,



and for how long" [4]. But this definition does not specify who will implement, decode or access it. Therefore very often used definition of prescription that is taught to the second year of medical students all over the world involves pharmacist as a main decoder and to a nurse or patients for administration [5, 6]. Even the "Rx" considered as the abbreviation of the word "recipere" which has a meaning of "take" or "take thus" is actually a direction for the pharmacist [5]. That means in a doctor-patient relationship first person is the physician who writes the therapy for the second person the patient but cannot access it without the help of a third person pharmacist forming a loop. This loop of communication still exists in contemporary pre-compounded medicine days.

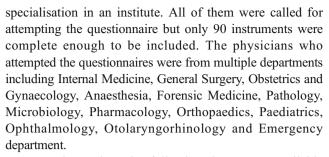
The knowledge of the prescription document elements is considered an expected and inborn talent in most of the prescriber in majority of the countries. Therefore prescribers are taught least regarding basic and regulatory aspects of the prescription writing formally in the medical schools [7, 8]. Some textbooks of basic, clinical pharmacology and medicine meant for undergraduate medical students contain a chapter or a section on prescription writing [5, 6]. The metamorphosis of a medical student into a prescribing physician starts with penning down the therapy for a patient on a prescription pad [9]. And it is also the beginning of the generation of most important clinical pharmacology tool.

It conventionally contains the written communication to the physicians, nurses and the patients [2]. In addition unconventional verbal non-pharmacological orders are also communicated necessary to adhered to the therapy and avoiding the risks and adverse events for safe medication but may become disadvantageous sometimes [10]. Incorrect or wrong prescription may have a serious life threatening consequences [11]. Lest aside the scenario in developing countries where prescription auditing is considered a taboo, the studies in developed nations have found approximately more than half of the hand written prescription as poorly readable or unreadable [12]. Other main reasons of prescription errors are medication documentation errors where wrong, missing date and time are frequent errors followed up by the missing dose specifications [12].

The present study was planned to get the knowledge and awareness of the serving physicians related to basic and regulatory aspects of the prescription writing in the tertiary care university teaching hospital.

### **Methods**

The sampling was done on a single tertiary care teaching hospital approved by the Medical Council of India (MCI). The MCI prescribe minimum number of the physicians in each department and in totality correspond to around 150 doctors in a 150 MBBS students college with varying degree of



A novel questionnaire following the present available guidelines [13, 14] regulating the prescription writing elements in India was prepared. There were 39 total questions containing 13 questions in each section (Tables 1, 2 and 3). Some questions have multiple queries. Each questionnaire needed an almost 30 min to completely cross checked the 70 statements in total. It was validated by applying it on the departmental faculty having minimum qualifications of MBBS. Three demonstrators and three senior faculty members participated in the validation. The questions were categorised into three different domains. First part contained the questions related to the general awareness of the physicians regarding the prescription writing. Second part had questions from the medicolegal requirement of the prescription elements as legal documents. The questions in third area were of ethical nature where there is no punitive action if wrongly committed by the physician and some action which are expected out of the physicians for the benefit of the patient for healthcare accessibility.

The questionnaire was given to the subject professionals for content validity. They were given the option to edit the stem of the questions in relation to importance of the topic, language phrasing and appropriateness. The questionnaire was finally amended and all their feedbacks were incorporated. Subsequently the questionnaire was assessed on Flesch Reading Ease Score available on computer software (Microsoft 2016) for the readability. Finally it was assessed for face validity by short post-questionnaire interviews with 10 Junior Residents (representative population) in different clinical departments. They were asked about its instructions, length, pattern of responses, ease of completion, completion time and questions difficulty level. They were given the chance to raise queries and ask questions related to questionnaire items.

Again it was checked by six teaching staffs in the department including three demonstrators (qualification MBBS) and three senior faculty (qualification MBBS, MD Pharmacology) for the clarity of the language and content of the questionnaire. They also attempted the questionnaire immediately after checking it followed up by again completing it on the 7th day for reliability testing. Their internal consistency was analysed by Cronbach's alpha value which was beyond 0.9 for satisfactory inclusion.



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 Table 1
 General awareness of doctors related to the prescription writing

S. no.	Statement	Yes (n/%)	No (n/%)	Don't know (n/%)
1	Prescription is an Order for			
	Pharmacist	36(40.00)	30(33.33)	24(26.67)
	• Nurse	8(8.89)	28(31.11)	54(60.00)
2	Prescription is a written order given in			
	<ul> <li>Out Patient Department – followed up by the Pharmacists</li> </ul>	30(33.33)	48(53.33)	12(13.33)
	• In Patient department – followed up by the Nurse	10(11.11)	32(35.56)	48(53.33)
3	Prescription by a doctor is a legal document	68(75.56)	16(17.78)	6(6.67)
4	Doctor Should write Statements concerned with pharmaceutical products on prescription such as:			
	Keep Refrigerated/ Store at 25degree	28(31.11)	12(13.33)	50(55.56)
	May cause drowsiness	40(44.44)	38(42.22)	12(13.33)
	Shake well before use	36(40.00)	50(55.56)	4(4.44)
	• Expiry Date	16(17.78)	68(75.56)	6(6.67)
	Quantity in the package	36(40.00)	50(55.56)	4(4.44)
	Take complete or full course	76(84.44)	14(15.56)	0(0.00)
	Take with or without food	88(97.78)	2(2.22)	0(0.00)
5	Prescription is governed by:			
	• The Indian Medical Council (IMC) Act, 1956	34(37.78)	44(48.89)	12(13.33)
	• The IMC (Professional Conduct, Etiquette & Ethics) Regulations, 2002	50(55.56)	10(11.11)	30(33.33)
	• The Drugs and Cosmetic Act, 1940 and Rules 1945	46(51.11)	12(13.33)	32(35.56)
	• The Pharmacy Act, 1948	52(57.78)	8(8.89)	30(33.33)
	<ul> <li>The Narcotics Drugs and Psychotropic Substance Act, 1985 and Rules 1987</li> </ul>	46(51.11)	12(13.33)	32(35.56)
	• Drugs (Price Control) Order, 1995	34(37.78)	12(13.33)	44(48.89)
	• The Drugs and Magic Remedies (Objectionable advertisement) Act, 1954 and Rules 1955	30(33.33)	16(17.78)	44(48.89)
6	Prescription blank or pad should have minimum size of A5 as per the MCI regulation	54(60.00)	20(22.22)	16(17.78)
7	Purchasing of Over The Counter (OTC) drugs requires a Prescription	50(55.56)	32(35.56)	8(8.89)
8	Advertisement of Claims of Good Hospital and best doctors can be added at the end of the prescription	20(22.22)	58(64.44)	12(13.33)
9	Rx symbol is a	26(40.00)	20/22 22	24/26 (5)
	• Sign of Jupiter	36(40.00)		24(26.67)
10	• Eye of Horus	30(33.33)	32(35.55)	28(31.11)
10	Parts of Prescription	26(40.00)	474.44	50/55 50
	Superscription is for the Doctors	36(40.00)	4(4.44)	50(55.56)
	• Subscription is for the Pharmacists	32(35.56)	8(8.89)	50(55.56)
	• Transcription is for the Patients	38(42.22)	2(2.22)	50(55.56)
11 12	If Pharmacist misread the handwriting of the doctors even then there are chances of doctor being found guilty  There is a difference between Prescription error and Prescribing faults	26(28.89) 68(75.56)	56(62.22) 6(6.67)	8(8.89) 16(17.78)
13	Divide the prescription as	30(,3.30)	0(0.07)	- 3(2,1,0)
10	Superscription, Inscription, Subscription, Transcription and Signa	44(48.89)	16(17.78)	30(33.33)
	Header, Body and Closing	26(28.89)	18(20.00)	46(51.11)
	Trouble, Doug and Crosing	20(20.07)	10(20.00)	10(31.11)

The questionnaire was qualitative with yes/no/don't know options as it was exploratory in nature because we were unaware about the general attitude of the respondents. We were assessing knowledge of the participants depending on the competency gained during their training and work experiences involving human elements vis a vis a concrete information based on the guidelines.

The Likert scale was unsuitable in this case as a person having knowledge will opt for yes/no but person without clear understanding will mark the option don't know. Sample was taken for more about generating the information by richness of data rather than the number of respondents or sample size for generalizability. It was to capture the multiple realities concerned with this



Table 2 Legal requirement awareness of the doctors related to the prescription as per the Indian guidelines

S. no.	Statements	Yes (n/%)	No (n/%)	Don't know (n/%)
1	Details printed on the prescription pad related to the Doctor			
	• Full name of the doctor	80(88.89)	8(8.89)	2(2.22)
	Address, Telephone, Contact numbers	86(95.56)	4(4.44)	0(0.00)
	Consultation Time and Date	84(93.33)	4(4.44)	2(2.22)
	All doctor's degree especially the primary degree	82(91.11)	6(6.67)	2(2.22)
	• Doctor's registration number and name of the registration council	86(95.56)	4(4.44)	0(0.00)
2	Prescription serial number	80(88.89)	8(8.89)	2(2.22)
3	Details written by the doctors on the prescription related to the patients			
	Patient's full name	86(95.56)	2(2.22)	2(2.22)
	Patient's Age, Weight	86(95.56)	2(2.22)	2(2.22)
	• Patient's Sex	82(91.11)	6(6.67)	2(2.22)
	• Patient's address and telephone number including his/her mobile number	56(62.22)	4(4.44)	30(33.33)
4	Writing or printing Rx on the prescription pad	72(80.00)	14(15.56)	4(4.44)
5	Cross-Prescribing (Prescribing a drug of a different system of Medicine such as Ayurveda, Homeopathy) is Illegal	56(62.22)	20(22.22)	14(15.56)
6	Details written by the doctors on the prescription related to the drugs			
	• Full name in Generic	72(80.00)	8(8.89)	10(11.11)
	• Full name in Capital letters	68(75.56)	10(11.11)	12(13.33)
	Strength or Potency	48(53.33)	26(28.89)	16(17.78)
	Dosage and dosing instructions	84(93.33)	4(4.44)	2(2.22)
7	Writing "as and when required" instead of S.O.S and full form of other abbreviations	56(62.22)	22(24.44)	12(13.33)
8	Writing total quantity of Medicine to be taken	78(86.67)	4(4.44)	8(8.89)
9	Writing refill information for Pharmacist as "SHOULD BE REFILLED TWICE/THRICE"	54(60.00)	16(17.78)	20(22.22)
10	Writing "DO NOT DISPENCE MORE THAN TWICE" in the middle of the prescription for habit forming drugs	60(66.67)	14(15.56)	16(17.78)
11	Leaving a space for Pharmacist to put his stamp and information for Dispensing	60(66.67)	14(15.56)	16(17.78)
12	Doctor's signature, address and date in blue indelible ink only	60(66.67)	12(13.33)	18(20.00)
13	Doctor's rubber stamp containing his full name, qualifications and registration number below his signature	74(82.22)	8(8.89)	8(8.89)

uncharted complex topic. The focus was to select purposively valid respondent rather than the number of people to attain data saturation.

The queries were kept very simple positive statements as the participants were Junior Residents, Senior Residents and Senior Consultants. Each query had short comprehensive language for their easy understanding as per the professional parlance. The readability of the questionnaire was checked by the Microsoft word 2016 document's The Flesch Reading Ease and The Flesch - Kincaid Grade Level scores. The Flesch Reading Ease score was 37.4 which were just above the understandable levels (0-30) of university graduates and appropriately lower levels for the professional subject. The Flesch – Kincaid Grade Level of 11.2 was suitable for average skilled participant (12–18 for skilled participants). It was printed on four A4 sheets for easy readability. However, only 90 questionnaires were found to be complete and finally included in the analysis. Descriptive analysis was done by SPSS 25 software.

#### Results

The result in Table 1 shows the dilemma of physicians that they are not sure who the prescription order is written for. There is no clear cut agreement over who is the final decoder of the prescription among the nurse and/or a pharmacist. It is shocking that some 22% doctors do not consider prescription order as a legal document. Contrastingly majority of the doctors (55.56%) think that patient access to the over the counter (OTC) drugs require their prescription. Question number 4 and 5 of the Table 1 contains the statements which every doctor ought to write wherever necessary on the prescription pad and the statutory acts applied on the prescription respectively. Table 2 askes the questions which are regulatory in nature and Table 3 has moral dos and don'ts for doctors. There are no documented specificities available in medical world for the question number 13 of the Table 3.

Majority of the participants believe that drug such as Letrozole (62.22%) and Sildenafil (66.67%) should not be



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 Table 3
 Some actions which are not punitive or some actions expected from the doctors

S. no.	Statement	Yes (n/%)	No (n/%)	Don't know (n/%)
1	Error of Omission and error of Commission	52(57.78)	14(15.56)	24(26.67)
2	If having only primary MBBS degree			
	Can prescribe anticancer drugs such as Letrozole	10(11.11)	56(62.22)	24(26.67)
	Can prescribe erectile dysfunction drug such as Sildenafil Citrate	16(17.78)	60(66.67)	14(15.56)
3	Prescribe medicine over telephone and SMS	10(11.11)	74(82.22)	6(6.67)
4	Allow Nurses and relatives to write drugs on his prescription pad in some situation	0(0.00)	90(100)	0(0.00)
5	Can put two more doctor's name on the same prescription	24(26.67)	56(62.22)	10(11.11)
6	Writing prescription for himself in his own handwriting for the drugs other than OTC	16(17.78)	58(64.44)	16(17.78)
7	Can use another doctor's prescription for his patients in emergency	20(22.22)	46(51.11)	24(26.67)
8	Write dosage forms (Tablet, Injection) on the prescription	80(88.89)	6(6.67)	4(4.44)
9	Write potency of the drug even if single medicine is prescribed	64(71.11)	14(15.52)	12(13.33)
10	Mention the separate potency if it is combination product (e,g. Ampicillin+Cloxacillin 250 + 250 instead of AmpiClox 250 as it may mean 125 + 125)	50(55.56)	22(24.44)	18(20.00)
11	Use of Initials for Overwriting	54(60.00)	18(20.00)	18(20.00)
12	Write "Continue Same Treatment or CST" or "For long Term Use" for same prescription again	54(60.00)	24(26.67)	12(13.33)
13	If patient is allergic to any Drug e.g., Penicillins. It should be written in which part of the prescription pad to communicate it to other physician			
	Superscription	80(88.89)	6(6.67)	4(4.44)
	• Inscription	5(5.55)	66(66.67)	19(21.11)
	• Header	70(77.77)	10(11.11)	10(11.11)
	• Footnote	32(35.56)	38(42.22)	20(22.22)
	• Boxed	64(71.11)	0(0.00)	26(28.89)
	• Underlined	48(53.33)	8(8.89)	34(37.78)
	• In Capital letters	68(75.56)	0(0.00)	22(24.44)
	• With some specific colour	60(66.67)	6(6.67)	24(26.67)

prescribed by a simple graduate physician. Most of the physicians do not have agreement regarding how to write and what should be the site of notification of allergic reaction on the prescription pad for the information to the fellow colleagues and other healthcare providers.

# **Discussion**

Prescription is the most important clinical pharmacology tool in the patient care access. And it is a legal document as well. However it is very unfortunate that there is still an ambiguity for which the prescription is written for whether it is direction for the patient or pharmacist. Some textbook says that pharmacists act as a decoder to the information enshrined by the physician in that instrument. And that it is divided into Superscription, Inscription, Subscription, Signa each meant for a difference person like doctors, pharmacists and patients respectively. Even the directions to the patients written by the treating physicians are not for the patients to read but for the pharmacists to tell the patients [5, 6]. The most of the emergency services have their cache of medicines and nurse directly follows the prescription orders. There is no intermediary in

case of Intensive Care Unit setting where nurse directly follows the prescription order. Thus the definition and scope of prescription order needs a revision and final format.

The Table 1, question number 4 contains the statements mentioned in the regulatory guidelines which a prescriber should write on the prescription sheet. However such commands become the part of the verbal prescription order given along with the main prescription pad. Even the prescription pad is divided into header, body and closing now a days. A uniform pattern should be implemented throughout the world.

We assumed that every doctor must have a hundred percent clarity over the legal aspects of the prescription writing but the data obtained were chaotic as participants were totally unaware about the facts and just using logical reasoning to answer. The writing patient's age, weight and sex is not a legal requirement as per the Government of Goa (GoG) guidelines. But participants scored more than 90% for agreement that this information is legal requirement. The writing prescription serial number and Rx are not legal requirement but a score of 88.89% and 80% was obtained on the contrary for each respectively (Table 2). These elements are also given as a part of the model prescription format issued by the Government of



Maharashtra (GoM). The refill information and dispensing direction for habit forming drugs are not legal in India.

In addition to that leaving a space for pharmacist for dispensing information on the prescription paper is not a legal requirement but model prescription format by the GoM and MCI (federal government institution in India) has a designated space and information for that. Allopathic physician very commonly writes drugs of Complementary and Alternative Medicine (CAM) despite being defined it as an illegal activity [15, 16]. Even in this study 20% of the physicians considered cross-prescribing as Illegal. Surprisingly writing drug dosage forms of the medicine is not a legal necessity. The guidelines say that doctor should sign as close to as the last drugs written, some form of error of omission and commission is not punitive and 57.78% participants are in agreement (Table 3).

It has been seen that incomplete training of the graduating physicians makes them more liable to make prescription errors [17]. Thus many hospitals accredited agencies lay stress on the prescription audit, prescription event monitoring and prescription errors as a separate chapter for quality standard for the accredited hospitals. Despite all necessary steps in corporate hospitals, medical litigations and violence against doctors are increasing day by day as the social cynicism is cherished more in some societies such as India against the traditional trust in the physicians [18]. More than 75% practitioners in their lifetime face some form of violence and few even get killed at the workplace [19, 20].

This may be attributed to the transitional shift in increasing patient's autonomy from the benevolent paternalism of the doctors [21]. Thus physicians have to be more realistic towards the distorted patient's perception in current times. The prescription pad elements are being more closely monitored and defined by the regulatory agencies corresponding to the increasing medicolegal understanding of the patients [13, 14, 21].

The federal government of India still needs to prepare comprehensive basic and regulatory rules for the prescription writing. Till date a single state GoG has released their guidelines in 2012 for the prescription writing while GoM and Medical Council of India (MCI) has released the model format of the prescription few years back. The judicial system in India is awarding punishment for doctors without any robust system of calculation of compensation. The court can award any amount of compensation. In one such court judgement against the doctors and the serving hospital, they were asked to pay \$1,574,123.60 to the deceased family for wrongful death in 2014 [22]. Similar is the trend for rising litigation for negligence and medication errors.

The things are pacing very fast in the Indian society towards accessibility of medical services, patients' rights and fencing doctor benevolent paternalism. The government is planning to release patient's charter prepared by National Human Right Commission which will further define patients'

rights enforceable by law. They have mentioned 17 patients' rights in a draft document in August 2018. These are right to information; right to records and reports; rights to emergency medical care; right to informed consent; right to confidentiality human dignity and privacy; rights to second opinion; rights to transparency in rates, and care according to prescribed rates wherever relevant; right to non-discrimination; right to safety and quality care according to standards; right to choose alternative treatment options if available; right to choose source for obtaining medicines or tests; right to proper referral and transfer, which is free from perverse commercial influences; right to protection for patients involved in clinical trials; right to protection of participants involved in biomedical and health research; right to take discharge of patient, or receive body of deceased from hospital; right to patient education and right to be heard and seek redressal [23].

It will lead to drastic change in healthcare accessibility and notion of doctor-patient relationship in India. Some of the drastic changes in patient's autonomy as per this document are providing the patients available options of treatment and management by the physician out of which patient can himself refuse or opt any particular therapy. And he can also ask for voluntary discharge for which he will be responsible for consequences, Itemized bills, expected cost of treatment beforehand including any expected change in physical conditions during the treatment, discharge and compensation in biomedical research.

We have conducted this study to gain the insight of prescribing without the inherent knowledge of basic and regulatory guidelines of prescription writing as doctors are getting harsher punishments from the court of law. One physician couple discharged the post-caesarean patient and prescribed the medicine over telephone in absentia subsequently to the Nurses, Chemist and patient without making the diagnosis of complication of pulmonary embolism. The patient died and court of law held it a criminal negligence of culpable homicide awarding the husband-wife physician duo a life imprisonment in July 2018. Table 3 of our study contains a question no. 3 that prescribing over phone in an established patient-doctor relationship is not punishable as per the existing guidelines but doctors should have avoided it [24].

In another such verdict three doctors were found negligent on account of not recognising drug allergic reactions and fails to start an initial warning on the prescription related to the immediate history of allergy to a particular group of drugs and prescribed the excessive large doses of drugs which aggravated the condition in which patient lost her life. Supreme Court awarded highest compensation till date of 11.41 crores rupees including interest (Approx. 15, 74,123.60 USD) on October 2013 [25].

Some practices such as Cross Prescription (Prescribing medicine of another system) have not met a harsher punishment till yet but they have been declared as Illegal by the



Supreme Court of India in as early as 1998 but still followed by practitioners of both the sides Allopathic as well as Complementary and Alternative Medicine (CAM) due to inadequate training of medical practitioners [26, 27].

The lack of disconnected regulatory guidelines in India has led to the confusion related to the teaching of prescription writing to the budding physicians as these guidelines do not make it legal to mention the very basic history taking of demographic parameters such as patient's age, weight and sex. The rationality of using Rx symbol in the prescription as a sign of Jupiter or eye of Horus, when it is not a legal requirement, needs further deliberation and scrutiny. The refill information and dispensing of habit forming drugs should come under the ambit of legal requirement all over the world including the developing countries.

Prescription writing metamorphosed a medical student into a prescriber physician. It is the most important evidence for prescribing fault and prescription error and a clinical pharmacology data. However rising violence, litigations against doctors, increasing patient's autonomy, pre-compounded medications and scrutiny of physicians' decision making necessitates that every element of prescription needs a precise and clear definition. The flow of information needs to be in the direction from doctor to the patients and then to other service providers such as pharmacists or nurse rather than forming a loop from physician to pharmacist through the patients.

## **Conclusions**

Our study clearly shows that the treating physicians are not unanimous on what is required and what is not in the prescription. Even the very basic information that OTC does not need a prescription is contested. Therefore preparing teaching modules for the training for basic and regulatory aspects of prescription writing is paramount in physician training. Second a straight communication needs to be developed between the doctor and patient with comprehensible and lucid terminologies and additional standard guidelines for prescription writing with standard definition are needed for better patientcare. Thirdly some areas need to be qualified such as writing a statement for patient's known allergy, its place of writing, colour of the writing ink, letter case of the font used and use of box or underline. And fourth the quantum of error of omission and commission that is not punitive needs objective identification.

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## Compliance with ethical standards

Conflict of interest None.

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