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Original Research Article

Ascertain Fundamental and Legal Knowledge about the Art of Prescription Writing in Tertiary Care Hospital

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Abstract

Background- A medical student to become a prescribing physician, must acquire both the fundamental and regulatory understanding of prescription writing. Prescriptions become the most significant clinical pharmacology tool and proof of pharmaceutical access, prescription errors, prescribing errors, negligence, and subsequent litigations. Given the rising violence against doctors in India, a cross-sectional questionnaire-based study was conducted to assess participants' understanding of the fundamental and legal aspects of writing prescriptions.

Methodology- The basic and regulatory knowledge and awareness of 90 doctors was evaluated for arts of prescription writing by a novel questionnaire based on Indian regulatory guidelines. It was assessed for content validity and reliability. 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- Doctors' knowledge of writing prescriptions is very limited. Most doctors do not knew that over-the-counter drugs do not require a prescription, that a pharmacist is the one who decodes their written prescriptions, that it is illegal to cross-prescribe (write a prescription for a drug from another system of medicine), or that they should not transcribe prescriptions over the phone.

Conclusion- Prescription mistakes plague the practice of writing prescriptions for medication access. The doctors' grasp of prescription writing basics and regulations is poor. It is therefore necessary to train them in prescription writing through standardized worldwide teaching modules. Prescription communications between physicians and patients must adhere to national regulatory requirements and be clear, accessible, thorough, and direct.

Keywords- Prescription writing, teaching pharmacology, Prescription elements, General practice.

Introduction

According to estimates from the National Health Services in the United Kingdom, the most popular therapeutic strategy provided to patients in general practice healthcare is prescribing [1]. In the majority of countries, handwritten paper prescriptions remain the primary means of communication between doctors, pharmacists, and patients. [2]

It consists of two parts: prescribing, which is the decision-making process, and prescription, which is the writing-related portion [3]. "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" is the definition of a prescription [4]. However, it is unclear from this definition who will access, decode, or implement it. As a result, the concept of a prescription that is most frequently taught to second-year medical students worldwide includes a pharmacist as the primary decoder and a nurse or patient for administration.

Even the letter "Rx," which is thought of as an acronym for the word "recipere" and means "take" or "take thus," is really a directive for the pharmacist [5]. This implies that in a doctor-patient connection, the first person is the doctor who composes the therapy for the second person, who is the patient, but who is unable to access it without the assistance of a third party, the pharmacist, creating a loop. This communication loop persists in pre-compounded medical days of today.

Prescription writing is covered in some undergraduate medical student textbooks on basic and clinical pharmacology and medicine [5, 6]. Writing down a patient's course of treatment on a prescription pad is the first step in a medical student's transformation into a prescribing physician [7-9]. Furthermore, it marks the start of the creation

of the most significant clinical pharmacology instrument to date. [10]

Traditionally, it includes written correspondence with patients, nurses, and doctors [2]. Unconventional verbal non-pharmacological directives are also conveyed; these are important to follow the therapy and prevent risks and adverse events for safe medication, but they can occasionally be detrimental.

A dangerous, potentially fatal prescription error might have major repercussions [11]. Aside from the fact that prescription auditing is frowned upon in poorer nations, investigations conducted in wealthy countries have revealed that almost half of handwritten prescriptions are illegible or impossible to read [12]. Other common causes of prescription errors include incorrect medication documentation, which frequently includes the date and time missing, as well as missing dose parameters.

The purpose of the current study was to ascertain the physicians' knowledge and awareness of the fundamentals and regulations pertaining to writing prescriptions in the university teaching hospital for tertiary care.

Methodology

The National Medical Council of India (NMC)-approved single tertiary care teaching hospital served as the site of the sample collection. About 150 doctors overall with diverse specializations in a college of 150 MBBS students. Although all of them were contacted to undertake the questionnaire, only hundred of the doctors were ready to participate. Internal Medicine, General Surgery, Obstetrics and Gynecology, Anaesthesia, Forensic Medicine, Pathology, Microbiology, Pharmacology, Orthopaedics, Pediatrics, Ophthalmology, Otolaryngorhinology, and Emergency Department were among the departments represented among the doctors who answered the questionnaires.

A new questionnaire that complies with current criteria [13, 14] governing prescription writing elements in India was prepared. Tables 1, 2, and 3 shows results depicted in number and percentage. The study included 39 questions, with 13 questions in each section. It took about thirty minutes to cross-check all seventy statements on each form. Applying it to departmental faculty members who met the MBBS minimum qualification requirements validated it. Three senior faculty members and three demonstrators took part in the validation. Three distinct domains were used to group the questions. The first section of the questionnaire asked questions about doctors' general knowledge of writing prescriptions. The second section included inquiries on the prescription items as legal documents and the medico legal requirements. The third area's questions were ethical in nature, with no consequences for doctors who make mistakes and some expected actions on their part to improve patient care and accessibility to healthcare.

The subject matter experts were given the questionnaire to ensure its content authenticity. They were allowed to make changes to the question stem concerning the relevance of the subject, wording, and appropriateness. After a final revision to the questionnaire, all of their input was included. The readability of the questionnaire was then evaluated using the Flesch Reading Ease Score, which is accessible on computer software (Microsoft 2016). In the end, ten junior residents from various clinical departments—a representative sample of the population—were interviewed briefly after completing the questionnaire to evaluate its face validity. They were questioned regarding the instructions, duration, response pattern, simplicity of use, time required for completion, and difficulty of the questions. They had the opportunity to voice concerns and ask questions about the items on the questionnaire.

Six members of the department's teaching staff, including three demonstrators (MBBS qualified) and three senior professors (MBBS qualified, MD Pharmacology qualified), reviewed it once more to ensure that the questionnaire's wording and substance were clear. Because we didn't know the respondents' general attitudes, the questionnaire was exploratory in character and had yes/no/don't know alternatives. It was qualitative in nature. We evaluated the participants' knowledge in accordance with the standards, taking into account the competency they had acquired during their training and job experiences incorporating human factors. The Likert scale wasn't appropriate in this situation since someone with knowledge would select yes or no, while someone without a clear grasp would select don't know. The sample size was chosen more for the purpose of generalizability than for the number of respondents or data richness that was used to generate the information. Its purpose was to convey the various realities surrounding this obscure and multifaceted subject. Choosing purposively valid respondents was more important than figuring out how many people needed to be in the data to reach saturation.

To make it easier to read, it was printed on four A4 sheets. Ultimately, only ninety-nine surveys were determined to be complete and incorporated into the study. Using SPSS 25, descriptive analysis was carried out.

Results:

The outcome in Table 1 illustrates the predicament faced by doctors when they are unsure about the intended recipient of a prescription order. The nurse and/or pharmacist cannot definitively agree on who is the final interpreter of the prescription. The

startling fact is that 27% (14 % No and 13% not known) of doctors do not view prescription orders as official legal documents. In contrast, the majority of physicians (68 %) believe that a prescription is necessary for patients to obtain over-the-counter (OTC) medications.

Table 1: General awareness of Doctors related to prescription writing.

S.no.	Statement	Yes (%)	NO (%)	Don't know
1.	Prescription is an Order for			
A	Pharmacist	38	32	30
B	Nurse	10	34	56
2.	Prescription is a written order given in			
A	Out patiients dept followed by the pharmacist	32	45	23
B	Inpatient department followed by the Nurse	11	38	51
3.	Prescription by a doctor is a legal document	73	14	13
4.	Doctor should write statements concerned with pharmaceutical products on prescription such as			
A	Keep Refrigerated/Store at 25 degrees	26	13	61
B	May cause drowsiness	43	54	03
C	Shake well before use	36	23	41
D	Expiry date	18	29	53
E	Quantity in the package	39	54	07
F	Take complete or full course	65	13	22
G	Take with or without food	76	23	01
5	Prescription is governed by			
A	The Indian medical council (IMC) Act, 1956	32	32	36
B	The IMC (professional Conduct, Etiquette & Ethics) Regulations, 2002	43	11	46
C	The drugs and Cosmetic Act, 1940 & Rules 1945	47	12	41
D	The Pharmacy Act 1948	54	9	37
E	The Narcotics drugs & Psychotropic substance Act, 1985 & Rules 1987	41	11	48
F	Drugs (Price Control) Order 1995	32	14	54
G	The drugs & magic Remedies (Objectionable advertisement) Act, 1954 & Rules 1955	32	13	55
6	Prescription blank or pad should have minimum size of A5 as per the MCI regulation	53	21	26
7	Purchasing of over the counter (OTC) drugs require as Prescription	68	22	10
8	Advertisement of claims of Good Hospital and best doctors can be added at the end of the prescription	18	24	58
9	Rx symbol is a			
A	Sign of Jupiter	38	23	39
B	Eye of Horus	31	28	41
10	Parts of prescription			
A	superscription is for the Doctors	34	6	60
B	Subscription is for the Pharmacist	32	5	63
C	Transcription is for the patients	27	1	72
11	If Pharmacist misread the hand writing of the Doctors even then there are chances of Doctors being guilty	26	45	29
12.	There is a difference between prescription error and prescribing faults	58	8	34
13	Divide prescription as			
A	Superscription, Inscription, Subscription, Transcription and signs	42	16	42
B	Header, Body & Closing	28	16	56

Table2: Legal requirement awareness of the doctors related to the prescription as per the Indian Guidelines.

S.No.	Statements	Yes (%)	No (%)	Not known
1	Details printed on the prescription pad related to the Doctor			
A	Full name of Doctor	82	3	15
B	Address, Contact number	86	8	6
C	Consultation time & date	85	7	8
D	Degree of the Doctor	82	5	13
E	Doctor's Registration number, Name of Registration Council	87	4	9
2	Prescription serial number	81	6	13
3	Details written by the doctors on the prescription related to the patients			
A	Patient's full name	85	5	10
B	Patients age, weight	86	3	11
C	Gender of Patient	89	3	8
D	Address and contact number of patient	56	3	41
4	Writing or printing Rx on prescription pad	79	7	14
5	Cross- prescribing a drug of a different system of medicine such as Ayurveda, Homeopathy) is Illegal	57	5	38
6	Details written by the doctors on the prescription related to the drugs			
A	Full name in generic	72	11	17
B	Full name in capital	66	23	11
C	Strength or potency	45	26	29
D	Dosage and dosing instruction	87	5	8
7	Writing as and when required instead of S.O.S and full form of other abbreviations	57	22	21
8	Writing total quantity of medicine to be taken	76	5	19
9	Writing refill information for pharmacist as "Should be refilled twice/thrice"	54	24	22
10	Writing "Do not dispence more than twice" in the middle of the priscription for habit forming drugs	65	17	18
11	Leaving a space for Pharmacist to put his stamp and information for Dispensing	62	15	23
12	Doctors signature, address and date in blue indelible ink only	63	13	24
13	Doctor's rubber stamp containing his name, qualification and registration number below his signature	78	8	14

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

S.No.	Statements	Yes (%)	No (%)	Not known
1	Error of omission and error of commiission	54	18	28
2	If having only primary MBBS degree			
A	Can Prescribe anti cancer drugs such as Letrozole	18	65	17
B	Can prescribe erectile dysfunction drug such as Sildenafil citrate	15	64	21
3	Prescribe medicine over telephone & SMS	11	75	14
4	Allow nurses and relatives to write drugs on his prescription pad in some situation	2	93	5
5	Can put two more doctor's name on the same prescription	25	65	10
6	Writing prescription for himself in his own handwriting for the drugs	18	16	66
7	Can use another doctor's prescription for his patients in emergency	23	43	34
8	Write dosage forms (Table, injection) on the prescription	79	8	13
9	Write potency of the drug even if single medicine is prescribed	67	15	18
10	Mention the separate potency if it is combination products (eg. Ampicillin + Cloxacillin 250 + 250 instead of Ampiclox 250 as it may mean 125 +125)	52	24	24
11	Use of Initials for overwriting	56	15	29
12	Write "Continue same treatment or CST" or "for long term use" for same prescription again.	56	25	19
13	If patient is allergic to any drug e.g. Penicillin. It should be written in which part of the prescription pad to communicate it to other physician			
A	Superscription	82	4	14
B	Inscription	6	68	26
C	Header	72	11	15
D	Footnote	32	43	25
E	Boxed	68	19	13
F	Underlined	43	7	46
G	In capital letters	69	2	29
H	With some specific colour	64	7	29

The declarations that every doctor should write on the prescription pad whenever necessary and the statutory acts that are applied on the prescription are found in questions number 4 and 5 of Table 1. Table 2 poses regulatory-related issues, whereas Table 3 lists moral dos and don'ts for medical professionals. Regarding question number 13 in Table 3, there are no known medical specifics accessible.
The majority of participants think that a basic graduate physician shouldn't administer drugs like letrozole (65 %) and sildenafil (64 %). Regarding the format and location of the allergic reaction notice on the prescription pad most of the doctors were not in agreement.

Discussion:

The most crucial clinical pharmacology tool for patient care access is the prescription. It is also a legally binding document. It is regrettable, therefore, that the prescription is still written with uncertainty regarding the pharmacist's or patient's instructions. According to some textbooks, pharmacists interpret the information that doctors enshrine in that device. Additionally, it is separated into four categories: Superscription, Inscription, Subscription, and Signs, each of which is intended for a certain individual, such as a patient, a pharmacist, or a doctor. Even the instructions that the treating physicians write down for their patients are meant to be read by the pharmacists, not the patients themselves [5, 6].

The majority of emergency services keep a stock of medications on hand, and the nurses adhere to the doctor's orders. When a nurse in an intensive care unit follows a medication order directly, there is no middleman. Therefore, a definitive structure and adjustment to the definition and scope of prescription orders are required.

The statements that a prescriber should write on the prescription page are listed in Table 1, question number 4 of the regulatory requirements. Nevertheless, these directives are included in the spoken prescription order that is issued with the prescription pad. These days, even prescription pads are separated into header, body, and closing sections. All around the world, a consistent pattern ought to be used.

We took for granted that all doctors would be completely knowledgeable about the legal ramifications of prescribing prescriptions, but the data we collected were disorganized since the participants had no idea what the questions actually meant and were only responding logically. According to the standards set forth by the Government of Goa (GoG), recording the patient's age, weight, and sex is not legally required. However, individuals who agreed that this information is required by law scored higher than 90%. Although it is not legally required to write the prescription serial number and Rx, 88.89% and 80% of respondents, respectively, scored negatively for each (Table2).

These components are also included in the model prescription format that the Maharashtra government (GoM) has released. In India, it is illegal to provide refill details and dispensing instructions for medications that cause addiction.

Furthermore, while it is not required by law, the GoM and MCI (a federal government organization in India) model prescription format includes a space and information specifically designed for the pharmacist to dispense information on the prescription page. Despite the fact that complementary and alternative medicine (CAM) is considered an unlawful activity, allopathic physicians frequently write prescriptions for CAM medications [15, 16].

Even in this survey, 20% of doctors believed that cross-prescribing was unlawful. It may surprise you to learn that writing down the medicine's dose forms is not required by law. According to the standards, a doctor should sign a document that is nearly identical to the last prescription prepared; any kind of error, whether intentional or not, is not penalized; 57.78% of participants agreed (Table 3).

It has been observed that physicians who graduate with insufficient training are more likely to write prescription errors [17]. As a result, a lot of hospitals and certified bodies emphasize prescription audits, prescription event monitoring, and prescription errors as distinct quality standards for hospitals that are accredited. In certain nations, like India, social cynicism is valued more than the traditional confidence in physicians, therefore despite corporate hospitals taking all required precautions, medical lawsuits and violence against doctors are on the rise [18]. Over 75% of practitioners experience violence at some point in their lives, and a small number even lose their lives while working [19, 20].

This could be explained by the gradual movement away from the doctors' benign paternalism and toward an increase in patient autonomy [21]. As a result, doctors nowadays need to be more understanding of the warped patient's perception. In line with patients' growing medicolegal awareness, the regulatory bodies are keeping a closer eye on and defining the prescription pad aspects [13, 14, 21].

The Indian federal government still needs to draft extensive foundational and regulatory guidelines for writing prescriptions. The Medical Council of India (MCI) and the Government of Maharashtra (GoM) released the prescription model format a few years ago, however just one state, GoG, has produced rules for writing prescriptions since 2012. Without a strong mechanism for determining compensation, the Indian legal system punishes doctors.

Any sum of compensation may be granted by the court. In a 2014 wrongful death lawsuit, the doctors and the hospital they worked at were ordered to pay the deceased man's family $1,574,123.60 [22]. The pattern of increasing litigation for drug errors and negligence is similar.

In Indian society, progress is being made quickly in the areas of patient rights, medical service accessibility, and curbing physician paternalism. The National Human Rights Commission created a patient charter, which the government intends to publicize. This charter would further define patients' legally enforceable rights. In August 2018, they made reference to 17 patient rights in a draft paper.

These include the following: the right to information; the right to records and reports; the right to emergency medical care; the right to informed consent; the right to confidentiality, human dignity, and privacy; the right to a second opinion; the right to non-discrimination; the right to safety and quality care in accordance with standards; the right to choose an alternative treatment option if one is available; the right to choose the source from which to obtain tests or medications; the right to a proper referral and transfer free from skewed commercial influences; the right to protection for patients participating in clinical trials; the right to protection of participants in biomedical and health research; the right to take the body of a deceased person from a hospital

It will result in a significant shift in India's perception of the doctor-patient relationship and the accessibility of healthcare. Providing patients with options for treatment and management by the doctor, from which they can choose or reject any particular therapy, is one of the most significant enhancements to patient autonomy as per this statement. In addition, he has the option to request a voluntary discharge, for which he will be liable for any associated costs, itemized invoices, anticipated treatment costs (including any anticipated changes in his physical state throughout the course of the treatment), discharge, and remuneration for biomedical research. [23]

We have undertaken this study to obtain an understanding of prescribing without an innate understanding of the fundamental and legal norms for prescription writing, as physicians are facing more severe legal penalties. Without diagnosing a pulmonary embolism problem, a doctor-patient pair released the post-caesarean patient and gave the medication to the nurses, chemist, and patient over the phone while they were away. In July 2018, a court determined that the patient's death was the result of criminal negligence, culpable homicide, and sentenced the husband and wife physician team to life in prison. Question number three in Table 33 of our study states that although doctors should have avoided it, prescription over the phone in a well-established patient-doctor relationship is not illegal under current rules [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].a criminal negligence of culpable homicide awarding the husband-wife physician duo a life imprisonment in July 2018. Table Table33 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

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.

A medical student become a prescriber physician through prescription writing. It is the most significant proof for clinical pharmacology data as well as prescribing error and fault. But with the rise in violence, lawsuits against doctors, patient autonomy, pre-packaged drugs, and scrutiny of medical professionals' decisions, each component of a prescription needs to be defined precisely and unambiguously. Instead of creating a loop from doctor to pharmacist through the patients, the information flow should go from doctor to patient, then to other service providers like pharmacists or nurses.

Conclusion:

Our study unequivocally demonstrates that there is disagreement among treating physicians regarding

what should and shouldn't be included in the prescription. There is debate even over the most fundamental fact—that OTC products do not require a prescription. Thus, it is crucial to prepare teaching modules for the fundamental and legal aspects of prescription writing in physician education. Better patient care requires, among other things, the development of clear, concise communication between the physician and the patient as well as the adoption of new standard criteria for prescription writing that include standard definitions.

Thirdly, some fields require clarification, such as when writing a statement about a patient's known allergies, the writing location, the ink color, the font case, and whether to use a box or an underline. Fourth, the amount of non-punitive error in commission and omission requires objective identification.

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