

INTERNATIONAL JOURNAL OF RESEARCH IN PHARMACY AND CHEMISTRY

Available online at www.ijrpc.com

Review Article

LEGAL ASPECTS OF PATIENT COUNSELING: NEED OF THE HOUR

M. Sonal Sekhar^{1*}, K. Samiya Nazeer², J. Tintu Sara² and R. Saraswathi³¹Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal University, Manipal, Karnataka, India.²Department of Pharmacy Practice, Amrita School of Pharmacy, Kochi, Kerala, India.³Al-Shifa College of Pharmacy, Perintalmanna, Malappuram, Kerala, India.*Corresponding author: sonalsekhar@gmail.com

ABSTRACT

As the practice of pharmacy continues to move away from dispensing and move toward the wider area of pharmaceutical care, the pharmacist's professional responsibilities will also increase. Since the implementation of Omnibus Budget Reconciliation Act 1990 (OBRA'90) in US, various studies have evaluated the impact the law has had on pharmacy counselling practices. Studies using an interview design found that 38% to 40% of patients were counseled by pharmacists. It is important for pharmacists to understand OBRA'90 and counseling requirements. If pharmacists comply with these laws then the chance of potential liability can be reduced. Many pharmacists do not realize the legal, professional, and economic consequences of ineffectively incorporating patient counseling into their practice. Beyond the risks, the benefits of patient consultation promises to improve not only the quality of life for patients but to greatly enrich the profession of pharmacy.

Keywords: OBRA90, Patient counselling, Patient care, Pharmaceutical care.

INTRODUCTION

Over the past decades, the pharmacy profession had gone through various stages to conquer one of the relevant positions in the Health care system throughout the world. Earlier, pharmacy professionals called compounders were focused on the preparation, compounding, storage and dispensing of medicines. Presently the situation has changed in a way that pharmacy profession has moved from behind the counter to explore their excellence in the field of pharmaceutical care. Currently medical practitioners rely more heavily on medications than in the past. For these medications to work to their full potential, patients need to take them correctly. Pharmacists are the final health professionals contact for most patient receiving prescription medication. The pharmaceutical care implies all the pharmacy activities aimed at promoting right use of

medicines by patient in the right manner¹. From the definition itself it is well understood

that the pharmacist has a great role in improving patient medication adherence. Patient counseling is one of the most important tools for better pharmaceutical care. Knowledgeable patients exhibit increased compliance with drug regimens, resulting in improved therapeutic outcomes.

Patient counseling is defined as providing medication information orally or in written form to the patient or their representative on direction of use, advice on side effects, precaution, storage, diet and life style modification². It should be interactive in nature. The information is usually given verbally, may be supplemented with written materials. Good communication skills are needed to gain the patients' confidence and motivate the patient to adhere to the recommended regimen³.

Objectives of patient counseling

According to the Helper and strand, the promoters of the concept of pharmaceutical care in pharmacy practice, there are four criteria to be considered for providing pharmaceutical care to patients. One of them is the provider must be able to develop the relationships with the patients and other health care professionals needed to provide pharmaceutical care.⁴ Others are pharmacist must be seen as a professional, patient becomes an active participant in the treatment. There should be an increase in patient medication adherence/ compliance. The need for the medication should be understood by the patient. Patient must get a confidence in the pharmacist's knowledge and reliability. Pharmacist should have knowledge about the medications, direction of its use, any possible side effects etc.⁵

Evolution of the patient counseling concept in India

In the olden days itself, patient education activities were carried out by colonial chemists or pharmacist in an unorganized manner. In 1980, significance of patient counseling had struck the minds of hospital pharmacists in India. The Indian journal of hospital pharmacy (IJHP), the official publication of Indian Hospital Pharmacist's Association, had started popularizing the concept throughout the country. In 1982, after years of sincere effort and hard work Dr. B. D. Miglani has started the first M. Pharm programme in hospital pharmacy at Delhi College of Pharmacy now known as Delhi Institute of Pharmaceutical Education and Research (DIPSAR). In 1990's many institutions in South India initiated PG programmes in clinical pharmacy, thereby got popularized in the country. In 1999, as per the revised Pharmacist's oath practicing pharmacist are responsible for providing Patient counseling. During the period of 1997-2003, many institutions started PG programmes in various parts of the country^{1,6}. In 1996, Dr. K. G Revikumar took the initiative for establishing the first patient counseling centre in Government Medical college Hospital Thiruvananthapuram, Kerala. Within a short period, patient counseling centre could satisfy the patients by giving them the

valuable information for the right use of medications. But the success of this counseling centre could paved only a narrow way for the establishment of patient counseling centres all over Kerala. Soon after this, counseling centres were started in other hospitals in India like CMC Vellore, JSS hospital Mysore. In India, most of the counseling centers were started for academic purpose by hospitals where PG in clinical pharmacy programme was running. Clinical pharmacists' at JSS hospital and JSS community pharmacy have taken lead in providing structured patient education, Drug Therapy Monitoring, providing unbiased drug information to the doctors and reporting ADR. In Hindu pharmacy Goa, pharmacists have initiated patient counseling and health screening service activities. Apollo Group of pharmacies is also showing interest in providing counseling services to the clients. In the changing trends in Indian practice of pharmacy, it is important to analyze the prescribers' perceptions towards community pharmacists' for prospective professional liaison.^{6,7}

Legal aspects of patient counseling

OBRA 90 is the acronym of the Omnibus Budget Reconciliation Act. It was enacted in USA on 5th November 1990. There are three main parts to OBRA'90 that address pharmacist activities, and these include prospective drug use review, patient counseling, and maintaining proper patient records. The goal of OBRA'90 was to decrease health care costs while improving health care for Medicaid patients. In order to achieve the goal it was decided to improve patient medication therapy and decrease inappropriate prescribing. The US federal government made it mandatory that in order to get federal financial aid, the states have to implement OBRA 90 programs by January 1, 1993^{3,8}.

Under OBRA 90 pharmacists educate patients or their care giver on at least the following issues.

- i. Name and description of the medication
- ii. Dose, dosage form and route of administration.
- iii. Special precautions for the preparation, administration or use of medication by the patient.

- iv. Common severe side effects, adverse effects, interactions and contra-indications that may be encountered.
- v. Technique for self monitoring therapy.
- vi. Proper storage of the medication.
- vii. Prescription re-fills information.
- viii. Any action that should be taken in the event of a missed dose.

In 1994, the United States Pharmacopoeia (USP) established an Ad Hoc Panel on MC behavior guidelines. This panel was a subgroup of the USP consumer interest or Health Education Advisory Panel. The work of the Panel resulted in the development of patient medication counseling. Inventory delineating 35 behaviours that could be part of a patient counseling session. The behaviours are divided into 4 groups that structure the counseling session into Introduction of the session, content of the session, process followed, and conclusion of the session. Communication skills in pharmacy practice provide a complete overview of counseling skills, issues, and methods.

USP drug information advice for the patient provides an excellent resource for the patient oriented materiel, including pictograms, for use with hearing or language impaired patients. Also demonstration of certain equipments such as with use of inhalation aerosols, or insulin injections may be used to either educate or verify how a patient is using one of the products. For a patient encounter, some texts are prepared to assist the pharmacist in determining the most appropriate information such as Patient counseling handbook⁸.

Need of patient counseling in Indian scenario

Patient counseling can be considered as a skill or an art; but it would not be effective if it did not come straight from the heart. Before giving patient counseling, a pharmacist should first realize the necessity to promote patient counseling, what's needed to provide good counseling services and how to go about it. Patient counseling leads to a positive behaviour through which patient is motivated to improve medication adherence.

Rapid development of science and technology has opened the door to the clinicians for the better understanding of etiology and pathological basis of various diseases and

development of new molecules. Many times, clinician fails to pass it on the right manner to the patient to achieve the therapeutic goals. One of the major reasons for this can be the patient non compliance towards the prescribed treatment⁹.

It implies an understanding, how the medicine is to be used, its side effects, as well as the positive behaviors in which the patient is sufficiently stimulated to take the right medications in the right manner so as to enhance the quality of life and wellbeing. Non compliance due to underuse, overuse, misuse, abuse etc can lead to various consequences. Pharmacist has a great role in improving the patient compliance by replenishing them with the information of their medications through effective patient counseling^{10, 11}.

Internationally pharmacist are proving their professionalism by providing patient care services such as patient counseling, drug therapy monitoring, health screening services, and by providing unbiased drug information services to the doctor. In India pharmacist's activities are not up to the mark. In India, health care system has not yet recognized the pharmacist importance in providing pharmaceutical care through valuable patient counseling. Though it is a close association of function, doctors and pharmacist are not perceived as working together and many clinicians do not regard pharmacist as a potential member of the health care team⁶.

In recent times, new powerful effective drug formulations are marketed in specialized dosage forms like aerosol, patches, modified release formulations etc. These formulations have different absorption routes like nasal, vaginal, buccal, percutaneous etc. some medications are packed in specialized containers like inhalers, rectal foams with complicated dosage forms. Modern medicines have side effects, some insignificant, other serious or fatal. Patients who use this medication for the first time should have some knowledge about the route of administration, frequency, side effects, precautions, directions of use etc. Pharmacists are in an excellent position to provide such advice or patient counseling to patients. Through patient counseling, a practicing pharmacist at the hospital or community pharmacy can establish an effective therapeutic relationship and thereby improving the treatment adherence of

the patients.¹⁰ Unlike acute illness, the chronic illness require hospital stay, self monitoring, follow up, lifelong drug therapy, non pharmacological measures and several lifestyle modifications. Therefore patient counseling has becoming a growing need in chronic illness. Most prevalent chronic illness has a strong connection with specific behaviours such as smoking, diet, sedentary lifestyle, intravenous drug abuse etc. One of the main choices for the prevention and effective treatment of the chronic illness require changes in behavioral habits. Pharmacist should themselves familiarize with recent developments in the scientific study of the behavioral change. When providing medication counseling to patients with chronic illness, pharmacists must sensitive to the broad array of challenges the patients face. Pharmacist can also play an active role through counseling in some of the commonly seen chronic illness like hypertension, diabetes, coronary heart disease, dyslipidemia, asthma, epilepsy, rheumatoid arthritis. Earlier, physicians had the time and facilities for providing the adequate information about the prescribed drugs to the patients. Now physicians are too busy with lot of patients, diagnosis and other related aspects. Also consultation room does not have the sufficient space for carrying out the patient counseling as it is always crowded with people. Moreover patients are not in a position to grasp all the informations from the prescriber due to their physical tiredness, anxiety or worries about the disease or related aspects⁹⁻¹¹.

Expert patients: Some patients with chronic diseases are found to be capable and competent in using their medicines to treat the disease or patients. Such patients are called Expert patients. In countries like UK there are schemes to use these expert patients for the benefits of lay patients in self management programmes for chronic conditions like arthritis.

Limitations of patient counseling in India

India is a developing country, facing significant drug related problems due to poly pharmacy. This includes drug duplication, drug overdose, under dose, potential drug interaction. Major reason for this drug related problems include illiteracy and lack of adequate or proper information regarding the

usage of medications.⁵ One hurdle found in patient counseling is Doctor Dispensing, Schedule K of 1940 Drugs and Cosmetics Act permitted doctors in the early days of independence to dispense medication to their patients in the rural areas where pharmacist are not available. Since the last 2 decades, the problems of doctor dispensing is rising due to commercial interest especially in cities and becoming a big threat to the survival of many pharmacists. This problem needs to be addressed with policy makers to put an end to the doctor dispensing as the pharmacist and patients' ratio is satisfactory in the society at the moment⁶.

Now days, doctors are very busy in their duty due to heavy patient load. Their consultation time for each patient is not sufficient to explain about the usage, dose, side effects etc of the medications. In India, General practitioners have not yet recognized the role of clinical pharmacist in improving medication adherence. Pharmacist who are supposed to be the information providers and should act as vital link between patients and the prescribers are remaining as prescription fillers. This lenient attitude of the pharmacist motivated us to probe the attitudes and behaviours of the pharmacists towards patient counseling. In India, D. Pharm remains as the basic qualification of pharmacy education. Although the present D. Pharm qualification is sufficient to run the pharmacy, to meet the present complicated health care demands B. Pharm or M. Pharm is a must. Unlike US, Indians are not aware about the indispensable role of a clinical pharmacist in achieving good therapeutic outcomes by enhancing patient medication adherence through effective patient counseling. Moreover they treated pharmacists as individuals who engaged in compounding medications (as compounders). This ignorance can be completely wiped off from the minds of patients by the pharmacist by providing them with effective pharmaceutical care. In USA, OBRA emphasizes the legal aspects as well as importance of patient counseling. But in India, there is no such acts that strictly implement the need of patient counseling. But in 1970, Kelkar Committee Report recommended a small fee of half a rupee for dispensing prescription. This extra amount is charged for giving pharmaceutical care like patient

counseling to the patients. But due to unknown reason, it was not implemented. In the feedback sessions, many pharmacists expressed that since patient counseling is not legalized, they can't charge any extra amount for the information provided to the patients and also for dispensing. If any extra amount is charged and collected by oversight through bill, if the matter is brought to the notice of local Drugs Inspector, pharmacist may be penalized heavy amounts of penalties and sometimes even cancellation of their license. Because of these lacks of legality towards patient counseling, the effort for popularizing the patient counseling comes to an end^{12,13}.

Recommendations for patient counseling

As the current PCI President Dr.Suresh said, the country has the largest qualified pharmacists pool compared to the other developing countries like Africa and South Asia. While it is estimated by the World Health Organisation that funds to the tune of US\$ 2.5 billion will be needed to train the pharmacists in these countries, Indian government should tap the opportunity of allowing pharmacists to take assignments in these countries under a mutual agreement between nations facing a shortfall of healthcare workers.

A pharmacist can play a wider role in reducing fatalities arising out of medication errors, maternal healthcare, child immunisation programmes, besides controlling the spread of AIDS, HIV and tuberculosis. The government will be able to reduce the disease burden if their services are well utilised. Therefore the need of the hour is to sensitize the indispensable role of pharmacists in the healthcare space, he added. Community pharmacy is most accessible to public. The awareness of need of patient counseling should convey through community pharmacist is good. So rules for running the community pharmacy should modify.

Pharmacists who graduated before 90s are not confident to provide patient counseling. Now our pharmacy course is divided into B. Pharm, more oriented to industry and M. Pharm (clinical pharmacy), PharmD, more clinically oriented. This clinical people are more trained to give patient counseling and other patient services. We have more than 27,000 degree students and 2600 postgraduate students

graduates each year. And also by giving continuous education programme for diploma holders, we can make up the situation. So the number of professionals eligible for patient counselling is increasing. By making rules of patient care for pharmacists, opportunities for the profession increases.

Unlike pharmaceutical societies in developed countries, the state pharmacy council in India don't have prescribed professional standards for practicing pharmacist and guidelines to practice the profession. The pharmacy council of India should formulate prescribed professional standards and guidelines for practicing the profession. As community pharmacists have tremendous outreach to the public, they should start counseling the patients, interact and discuss their needs, provide information on medicines, diseases and offer psychosocial support. Psychosocial support needs to be integrated into the counseling process.

Patients may not see the importance of discussing how and when to take their medication with the pharmacist. Therefore, it is essential that the pharmacist promotes the importance of patient counseling. This can be done through various means:

- A poster can be put up in the pharmacy and or a pamphlet/card can be given to patients coming to the pharmacy, or the information can be incorporated in regular newsletter that a pharmacy provides patient counselling.
- The pharmacy can offer health screening facilities which promote patient counselling. For example, a pharmacy offering free blood pressure checks for its consumers specifically brings them to the pharmacist, with enough time and scope to initiate conversation during the act of measuring blood pressure. In this way, confidence in the pharmacist about their professionalism and approachability can be generated.
- Most patients feel that the pharmacists are always busy at the counter either attending to other, or dispensing. This perception will only change when the pharmacists clearly demonstrate that they have time for patients.

CONCLUSION

The pharmaceutical industry which has come up to a level of recognition now needs to take the assistance of pharmacists in the areas of promoting safe, effective, rational medicine use and patient counseling for India. Pharma Vision 2020 is designed to achieve this marvelous aim. Patient counseling is one of the effective ways to get into the heart of public the profession "pharmacist". In Indian set up nobody will do the things if there is no act to implement regulations to provide compulsory patient counseling and pharmaceutical care by qualified personnel. So, legal assistance is very much important by enacting a law by the parliament. Other foreign countries' including USA mandated patient counseling only after OBRA 90. So such requirement is extremely urgent to safeguard the health of our citizens.

ACKNOWLEDGMENT

The authors are grateful to the Manipal University, Manipal for providing all source support.

REFERENCES

1. Revikumar KG. Pharmaceutical care and pharmacy practice. *Indian J Hosp Pharm.* 2001;6:221-223.
2. ASHP. ASHP Guidelines on pharmacist-conducted patient counseling. *Am J Hosp Pharm.* 1976; 33:644-645.
3. ASHP. ASHP guidelines on pharmacist-conducted patient education and counseling. *Am J Health-Sy Pharm.* 1997;54:431-434.
4. Hepler CD and Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm.* 1990;47(3):533-543.
5. Roter DL, Hall JA and Merisca R. Effectiveness of interventions to improve patient compliance: a metaanalysis. *Med Care* 1998; 36: 1138-1161.
6. Sonal Sekhar M, Suja Abraham and Revikumar KG. Emerging trends in practice of patient counseling-Indian scenario. *Indian J Pharm Pract.* 2008;1(1):6-13.
7. Adepu R and Nagavi BG. General practitioners' perceptions about the extended roles of the community pharmacists in the state of Karnataka: A study. *Indian J Pharm Sci.* 2006;68:36-40.
8. Varstad BL, Bultman DC and Mount JK. Patient counseling provided in community pharmacies: effects of state regulation, pharmacist age, and busyness. *J Am Pharm Assoc.* 2004;44:22-29.
9. Subish Palaian, Mukhyaprana Prabhu and Ravi Shankar P. Patient counseling by pharmacist -a focus on chronic illness. *Pak J Pharm Sci.* 2006;19(1):62-65.
10. Lewis RK, Lasack NL, Lambert BL and Connor SE. Patient counseling – a focus on maintenance therapy. *Am J Health-Syst Pharm.* 1997;54(18):2084-2098.
11. Rasheed A, Ramesh A and Nagavi BG. Improvement in quality of life through patient counseling. *Pharma times.* 2002;34:9-10.
12. Lee AJ, Borham A and Korman NE. Staff development in pharmacist-conducted patient education and counseling. *Am J Health Syst Pharm.* 1998;55:1792-1798.
13. Mishra P, Subish P, Upadhyay DK, Bista S, Alam K and Bhandari RB. Medication counseling center in a teaching hospital. *J Nepal Med Assoc.* 2005;44(160):129-134.