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**INDIAN JOURNAL OF PHARMACY PRACTICE**

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## Editorial

*“From small beginnings come great things”*

*Heartiest greetings to all fellow pharmacists, academicians, researchers and students!*

*It is indeed a great privilege and an honor for me to be addressing you all at the historical event of launching the first ever journal of the country exclusively devoted to Pharmacy Practice.*

*Pharmacy Practice is showing tremendous growth in the last few years. Good number of Institutions are offering M.Pharm in Pharmacy Practice and with the emergence of Pharm.D programme in the near future, the time seems to be just ripe for the upliftment of the profession of Pharmacy from merely production and dispensing to being an important member of the healthcare team. Also there are many more opportunities for the pharmacists with India becoming a hub for clinical trials.*

*Now that considerable work has been done in the area of pharmacy practice, there is a need of a forum to share the research findings, practice experiences and other relevant issues with the fellow practicing pharmacists and researchers. Considering this, it is commendable that **Association of Pharmaceutical Teachers of India (APTI)** has decided to launch a journal exclusively for pharmacy practice which will be published quarterly.*

*It is OUR journal and let us all join hands in contributing our research works/ practice experiences for the benefit of the professionals and make this endeavor a great success.*

*We need to have quality articles not only from India but from all over the world for good readership and to gain knowledge and update ourselves with the latest happenings in the field.*

*I take this opportunity to invite articles from you all in the relevant areas of pharmacy practice and also experts to come forward and register as reviewers.*

*As it is said “All glory comes from daring to begin” and “A journey of thousand miles must begin with a single step”, we have made a beginning and hopefully will make a mark in our profession of pharmacy through our good work and its publication.*

*On behalf of the Editorial Board, I request you all to patronize and encourage this beginning with valuable contributions and constructive criticism to perpetuate this publication and to help us to attain our objectives.*

**Dr. Shobha Rani R.Hiremath**  
Editor-in-chief



## Social Pharmacy- The Current Scenario

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### Abstract

This article considers the discipline of social pharmacy in the context of medicines and health and in the Indian context. It attempts to define social pharmacy and differentiate it from pharmacy practice. It then considers social pharmacy in the curriculum including the new Indian Pharm D curriculum. Social pharmacy research methods are then examined. Finally, the author's research on emergency hormonal contraception is discussed as an example of social pharmacy research.

We live in a rapidly changing economic, political and social world with widening inequalities in health. Disease patterns are changing and with an ever increasing older population and communicable diseases like HIV, AIDS, Malaria and TB continuing to prove difficult and costly to prevent and treat, the cost of providing health care continues to escalate. Adherence to long-term therapy for chronic illnesses is estimated to be 30-50%.<sup>1,2</sup> Non-adherence is often not discussed during pharmacy consultations, but may lead to worse health outcomes for the patient and to an increased economic burden. The World Health Organisation<sup>1</sup> highlight the need to develop strategies to improve medicines adherence as an essential element in reducing the global burden of disease. Studies on preventable medicines-related hospital admissions<sup>3,4</sup> indicate that problems occur at all stages of the medicines use process: prescribing, dispensing, administering, monitoring and seeking help. This is usually due to inadequate communication, knowledge gaps and errors. Around 4% of hospital admissions in the UK are due to medicines.<sup>3,4</sup> It is clear from research that patients' beliefs and attitudes influence how they use medicines.<sup>5,6,7</sup> Also, in many countries, significant changes have taken place with respect to healthcare systems and pharmacy profession. There is increased corporatisation of community pharmacy with respect to pharmacy contracts including the payment of cognitive services such as home medication reviews, minor ailment services and smoking cessation schemes. There has been a blurring of roles

between healthcare professionals, for example, pharmacist and nurse prescribing in the UK<sup>11</sup> leading to increased competition. It is evident that the pharmacy and health care world involves complex human interactions that can rarely be studied or explained in simple terms, this is very interesting to social pharmacists and has implications for both teaching and research.

If we consider India, there are a wide variety of models under which people obtain medicines, it may be from a village health worker and they may never see a pharmacist, they may buy medicines from a pharmacy operated but not necessarily run by a diploma trained pharmacist, at the other extreme they may receive pharmaceutical care from a highly trained clinical pharmacist operating as part of the healthcare team in a 'high tech' privately funded hospital. How people obtain their medicines and the advice they get may affect how they feel about and if they actually take their medicines and ultimately if they recover from an acute illness or maintain good health with a chronic condition. This and similar issues are some of the issues that social pharmacists like to research.

Social pharmacy draws on the theories and methodologies of the social and behavioural sciences. It can thus be conceived of as part of a socio-environmental or bio-psycho-social approach to understanding health and illness as distinct from the commonly accepted biomedical approach<sup>12</sup>. Social pharmacy might include for example theories and concepts from the areas such as communication, public health, sociology, ethics and behaviour. Social science based understandings are utilised to improve clinical practice, promote informed political awareness, develop professional and

managerial competencies, inform ethical judgements and engender a critical approach which encourages change and improvements in services and health care delivery.

There have been several calls for a definition of social pharmacy and to distinguish between social pharmacy and pharmacy practice, but, this does not seem to have been achieved.<sup>13,14,15</sup> Several authors have attempted to define social pharmacy, clinical pharmacy and pharmacy practice. For instance, Harding and Taylor<sup>16</sup> suggest that, in Britain, pharmacy practice provides the umbrella under which social pharmacy exists, whereas Mount<sup>17</sup> suggests that, in the US, social pharmacy (or social and administrative pharmacy) is a subset of the social sciences in pharmacy. Ryan and Bissell<sup>18</sup> call for more applied theoretical work in social pharmacy that could help with the development of a theoretical and conceptual knowledge base to inform research and teaching in the discipline.

#### **Social Pharmacy In The Pharmacy Curriculum**

In 1975, in the US, the Study Commission on Pharmacy (Millis Commission Report) identified the need to develop the behavioural and social sciences in pharmacy alongside clinical practice.<sup>19</sup> From 1975, the American Council on Pharmaceutical Education included pharmacy administration, social and behavioural sciences in their indicative curriculum. The most recent educational statement from the American Association of Colleges of Pharmacy incorporates many social and behavioural topics as required outcomes of pharmacy programmes in the US.<sup>20</sup> A number of European countries introduced social pharmacy into their curricula in the mid-1970's. In the UK, in 1986, the Nuffield Committee of inquiry into Pharmacy<sup>21</sup> declared that behavioural science should be incorporated into the undergraduate pharmacy curriculum. This was endorsed by the Royal Pharmaceutical Society (RPSGB) Working Party on Social and Behavioural Science.<sup>22</sup> Teaching of social pharmacy is now undertaken in all UK schools of pharmacy in the UK and forms part of the RPSGB's indicative curriculum. In our recent survey<sup>12</sup>, we used a web-based questionnaire to collect data on social science teaching in schools of Pharmacy. There were 62 responses representing schools of pharmacy from 17 countries. The social science disciplines appear to have gained in acceptance within the pharmacy establishment showing an advancing degree of sophistication and rudimentary development of a theoretical base. However, there was a wide range of subjects, from

scientific to behavioural, being taught under the banner of social pharmacy suggesting that there remains a lack of definitional agreement.

It is very interesting to note that the proposed Pharm.D curriculum for India<sup>23</sup> does not specifically mention social pharmacy. However, the section on the internship states that an objective is "to provide patient care in co-operation with patients, prescribers, and other members of an inter-professional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioural or administrative, and clinical sciences that may impact therapeutic outcomes. I believe that the omission from the curriculum may prove to be a wasted opportunity.

#### **Research Methods In Social Pharmacy**

Social pharmacy researchers use social science research methods. These may include quantitative methods such as surveys, but often also use qualitative research methods like interviews, focus groups, observation, documentary analysis and conversational analysis. Policy decisions are increasingly informed by findings from qualitative as well as quantitative research. Qualitative research is useful to policy makers because it often describes the settings in which policies will be implemented. Qualitative research is also useful to pharmacy practitioners as they develop their services. Qualitative research involves the collection, analysis and interpretation of data that are not easily reduced to numbers. These data relate to the social world and the concepts and behaviours of people within it. Qualitative research can be found in all social sciences and in the applied fields that derive from them.<sup>24</sup> It looks at what is X, how does X vary? in different circumstances rather than how big is X or how many Xs are there.<sup>25</sup> Text-books often sub-divide research into qualitative and quantitative approaches and it is often assumed that there are fundamental differences between the two approaches. With pharmacist's who have been trained in the natural and clinical sciences, there is often a tendency To embrace quantitative research, perhaps due to familiarity. However, a growing consensus is emerging which sees both qualitative and quantitative approaches as useful to answering research questions and

understanding the world. Increasingly mixed methods research<sup>26</sup> is being carried out where quantitative and qualitative research are used together in the same study and the researcher explicitly combines the quantitative and qualitative aspects of the study to both develop and test theories.

### **An Example of Social Pharmacy Research on Emergency Hormonal Contraception**

One of the projects that I have been involved was the evaluation of the two initial schemes for pharmacy supply of emergency hormonal contraception (EHC).<sup>27,28,29</sup> I worked alongside a social scientist on this project. There was considerable political concern about these government funded schemes aimed at reducing teenage pregnancy levels. However, in keeping with my belief that pharmacies could be a unique forum for improving access to services, I immediately saw these schemes as setting down a marker for pharmacists' involvement in other areas of practice development and public health. We used interviews with pharmacists and stakeholders, surveys and focus groups with women and a form of participant observation, mystery shopping to evaluate the services. Our evaluation of these schemes indicated that pharmacists were enthusiastic about this role and that they supply emergency contraception appropriately. Surveys with 745 women who had used the service indicated that they viewed the service positively. However, 15 percent of those surveyed, mainly those who were under 20 years, would prefer more privacy- something pharmacists have subsequently addressed with the provision of consultation areas. Majority of the women who used the service were not teenagers. Our findings also demonstrated that the increased access to emergency contraception via pharmacy means that it is more likely that women are able to take emergency contraception sooner after unprotected intercourse than when they obtain it from other sources. The largest number of consultations was at weekends or on Monday mornings when other services are difficult to access. In particular, the women surveyed noted a welcome absence of judgmental attitudes when accessing the service. However, both the women using the schemes and the pharmacists had a number of major concerns about the schemes, centering on the potential for misuse, changes in contraceptive behaviour due to the availability of EHC and the impact on sexually transmitted infections. More research is needed to explore these issues. A number of participants questioned the wisdom of the pharmacist providing advice

about long-term contraception needs and sexually transmitted infections in the context of the consultation. Some felt that the service should be confined to supplying emergency contraception rather than counseling individuals on their long-term contraception needs or the risks of sexually transmitted infections. In-depth interviews with pharmacists indicated that having a ten minute private consultation with women had changed women's perceptions of pharmacists, and possibly increased their professional status in the eyes of users. We have tried to seek an explanation for why pharmacists welcomed the scheme and also had strong reservations about it. Their positive attitudes towards the scheme may be a reflection of their desire to welcome and show competence in the delivery of new and innovative roles, important for the future development of the profession. We showed that providing a service which involved conducting a detailed and private consultation with women (and then supplying a product free of charge) was considered to be different to other services currently provided within community pharmacy. Not only did many pharmacists enjoy these aspects of practice, they also received remuneration for it without having to charge for the service. More than one participant argued that this potentially paved the way for the future delivery of other services, for example pharmacist prescribing and new funding streams. Others believed that the service had changed public perceptions of pharmacists, and this potentially enhanced their professional status. These factors are likely to be important to pharmacists, given the need to develop new roles and responsibilities in response to the historical threats to their professional legitimacy. Edmunds and Calman<sup>30</sup> have argued that the development of new roles and responsibilities is essential for pharmacy as a survival strategy. It is possible that pharmacists' attitudes to the schemes, at least to some extent, reflect these wider professional necessities. What we do not know is that the supply of EHC via pharmacy has met the policy objective of reducing teenage pregnancy in women from lower socio economic groups, many of the users were older women. However, our research has helped in the continued funding of these services and informed many primary care organisations in the UK who set up similar services for supply of EHC and Chlamydia screening and treatment services.

### To the Future

So what is the future for social pharmacy? I believe it is still a young and developing discipline. So long as people are seeking treatment, taking medicines and attempting to improve their health, there remains a rich resource for social pharmacy research and teaching. It is important that we work in collaboration with social scientists to develop research and teaching skills in this area.

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## Emerging Trends in Practice of Patient Counselling- Indian Scenario

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### Abstract

The profession of pharmacy and concept of pharmaceutical care are developing rapidly all over the world. Along with this, the responsibility of the pharmacist through utilisation of his technical and professional knowledge in promoting rational and prudent use of medicine is also increasing. It is well documented that safe and effective drug therapy occurs when patients are well informed about medications and their use. Patient counselling is an effective tool in educating patients about their medicines and promoting their scientific and proper use. The concept of patient counselling in its modern form originated in India in the mid 1990s. Since then, considerable growth and development occurred in the country in the area. Various factors contributed positively for setting the new trend in pharmacy practice. While matching with the international concepts, the Indian patient counselling practice has established its own characteristic features. From the hospital set ups, the concept has percolated deep into the community set ups in the very recent times. With the introduction of programs like Pharm D, there will be further growth and development in the area of patient counselling during the next decade.

**Key words:** Patient Counselling, Pharmaceutical care, Patient compliance, Emerging trends in Pharmacy Practice.

### INTRODUCTION

Throughout the world, over the past four decades, there has been a consolidated effort to shift the concept of pharmacy practice from its earlier focus on medicine supply to patient care. An important responsibility of contemporary pharmacy practice is to ensure appropriate and safe drug therapy which is cost effective and socially committed. By taking direct responsibility for individual patient's medicine related needs, present day pharmacists are contributing their professional responsibility to the positive outcome of drug therapy and to the patient's quality of life.

The pharmaceutical care implies all pharmacy activities aimed at promoting right use of medicines by patient in the right manner<sup>1</sup>. It stipulates that all practitioners should assume responsibility for the outcomes of drug therapy in their patients and encompasses a variety of services and functions. Some of these functions are new to pharmacy while others are traditional. The concept of Pharmaceutical care also includes emotional commitment to the welfare of patients as individuals who require and deserve pharmacists' compassion, concern and trust. The basic philosophy of pharma-

ceutical care is caring for a patient's drug therapy and related needs. Patient counselling is an integral component of pharmaceutical care.

### Indian Scenario

India is a developing country with over one thousand lakh population. The country is facing many new challenges in terms of burden of diseases, limited resources, increasing cost of health care and irrational use of medicines. There are thousands of brands in various therapeutic classes of medicines and over one lakh different formulations and their combinations in Indian drug market<sup>2</sup>. Unlike some developed countries like U.S., in India, the prescribers are still practising brand prescription style rather than the generic system. Most of the patients could not understand the information on the labels and package inserts. The concept of bioequivalence and its relevance in promoting cost effective drug therapy is not yet adopted or popularised in the country. Very few hospitals have adopted the hospital formulary system promoting generic dispensing. The culture of professionalism in its real perspective is not widely practiced and followed in community pharmacies, though the trend has already initiated in various parts of the country. The practice of clinical pharmacy designed in the way that is best suited for

indian environment can readdress these problems in the very near future.

Pharmacists being the first point of contact in the community set up and last point of contact in the hospital set up are in a competent position to influence the patient to a large extent. The essential role of a practicing pharmacist, especially, in community and hospital pharmacy set ups, includes much more than the accurate distribution of medicinal products.

#### **Relevance of Patient counseling in India**

Apart from the availability of tens of thousands of formulations in the market, many new powerful and effective drugs formulated in specialised dosage forms like aerosols, patches, modified released formulations, etc, were produced and marketed in the country. Medicines are often packed in specialised containers like inhalers, rectal foams, etc., with complicated usage and dosage methods. Patients, to whom these medicines are prescribed, need special information and advice from the pharmacists in the hospital and community pharmacies. Most of the new generation of practising pharmacists in the country consider patient counseling as an essential component of the dispensing activities. Many of them have already proved that through counseling, pharmacists can establish an effective therapeutic relationship with the patients.

Earlier it was obligatory for the physicians to provide all information about the drugs they prescribed to their patients. Till 1960s, the physicians in the country had the time and other facilities for providing such services. Today, the situation is totally different. The physicians are too busy with diagnosis and other related aspects. The doctors' consultation room has become unsuitable for patient counseling for various reasons. The writing of prescriptions is considered as a symbolic act, signifying the end of consultation. The patient is not in a position to listen to all the information given by the doctor related to his medicines because of the physical tiredness, anxiety, worries about the disease or related problems, when he is with the doctor for the first time. In some cases, the prescriber gives excellent and comprehensive information, but because of the stress and tension, the patient fails to take in all the information or retain it. Patient counseling is an essential professional requirement for the hospital and community pharmacies in the country, though presently there is no mandatory requirement for such services in India.

#### **Genesis of the concept of modern patient counseling concept in India**

Right from the days of colonial chemists, educated and

qualified pharmacists and chemists were engaged in patient education activities in India, though not in an organised manner. Pharmacists and chemists from other countries who came to India to work in the hospitals or the community pharmacies enjoyed discussions with the patients about their medicines in the early 1900s. Indian chemists and pharmacists who own their own community pharmacies also practiced the 'patient education' activities. Quite often, the public and the patients approached the 'chemists', 'compounders' and apothecaries for their advise on health related matters.

By 1980s, Indian hospital pharmacists became aware of the concept of patient counseling services and their relevance, though the community pharmacists were not educated in that line. The Indian Journal of Hospital Pharmacy (IJHP), the official publication of Indian Hospital Pharmacists Association, contributed considerably in popularising the concept in the country. However, there was no progress in establishing separate patient counseling centers attached to hospital pharmacies or community pharmacies, though some established hospital pharmacies initiated the Drug Information services attached to the hospital pharmacies in the 1960s and 1970s in India limiting their services mainly to the health care professionals.

In 1982, Dr. B.D. Miglani initiated the first M.Pharm program in Hospital Pharmacy incorporating clinical and community pharmacy at Delhi College of Pharmacy which is now known as Delhi Institute of Pharmaceutical Sciences and Research (DIPSAR), a deemed University of Delhi government. Later the Pharmacy Council of India (PCI) managed to incorporate certain principles of pharmacy practice in its revised 4<sup>th</sup> Education Regulations (ER 1991) for the two year Diploma in Pharmacy (D.Pharm) program. (see **Table 1**). The concept of patient counseling got popularised in the country only in the 1990s when many institutions in the southern states of India initiated post graduate programs in clinical pharmacy. Till then, the idea of promoting patient counseling was hampered by lack of competent and trained personnel. In 1999, when the Pharmacy Council of India celebrated 50 years of its existence, they have revised the Pharmacists Oath, setting new codes of concepts in pharmacy practice. As per the revised pharmacists Oath, the practising pharmacists are responsible for providing patient counselling. Countries like USA and Australia took three to four decades time to develop the skills and other backgrounds required to establish and popularise the concept of patient

counseling in their country<sup>3</sup>. In India, the concept has got acceptance within a short period of ten years which is considered as a good trend. With the objective of moulding a new generation of practice oriented pharmacy professionals, many institutions started pharmacy programs at the masters level during the period 1997- 2003 (see table 2).

#### **Trivandrum Experiment**

In 1996, for the first time, a separate patient counseling center was established in the Govt. Medical College Hospital, Trivandrum, attached to the Community pharmacy services of the department of Pharmacy Practice (Hospital and Clinical Pharmacy). This Department of Pharmacy Practice was the first of its kind in India started in 1992 by the Government of Kerala<sup>10</sup>. Starting of Patient Counseling Center was one of the specified objectives of starting the department. The Hospital and Clinical Pharmacy department started a professionally managed community pharmacy services inside the Medical College Hospital premises in 1995. To the surprise of all, the Community Pharmacy has grown and developed to one of the largest community pharmacies in Asia within the next couple of years time and more than one hundred post graduate, graduate and diploma pharmacists were employed there to look after the pharmacy practice activities. The patient counseling center was first started in a separate open area of the Community pharmacy. A team of five young pharmacists comprising of one M.Pharm, one B.Pharm and three Diploma pharmacists lead the counseling activities. These pharmacists were given three months training in the hospital and clinical department prior to their posting. It was started in a humble manner with a table, few chairs and certain essential reference books (see fig 1). Within a short period, people found the services of the center very much useful and beneficial for the right use of medicines. Long serpentine queue started appearing in front of the patient counseling center and by 1997, the center became a 24 hour service. A separate area, with two rooms was constructed for the counseling center and was developed as a training center for all levels of pharmacy students including research scholars (see fig. 2). The services of the center was well acclaimed. Media, both electronic and print, supported the center and reported its yeomen service to the society. The 'Hindu', a national daily, carried a feature on the working of the patient counseling center with photograph. Very soon, counseling centers and activities were started in other hospitals in India like CMC, Vellore; JSS Hospital, Mysore where post

graduate courses were conducted in clinical pharmacy. In the beginning counseling centers were located only in the hospitals wherever clinical pharmacy programme was running. Soon this was spread to community pharmacies as the post graduate students' undertook patient counseling studies in community pharmacy settings. A good number of interventional studies on the impact of patient counseling on chronic illness like diabetes, asthma and hypertension were conducted in community pharmacies during the period 1998- 2008. Counseling centers could make significant impact in the management of many chronic diseases in the country and it helped to popularise the concept of patient counseling in India. Some professional organisations like Indian Hospital Pharmacists Association (IHPA), Indian Pharmaceutical Association (IPA) and Association of Pharmaceutical Teachers of India (APTI) encouraged the concept through their official publications. In some states like Karnataka, Kerala and Maharashtra, the Pharmacy Councils also took steps to popularise the counseling activities in the community set ups.

#### **Counseling centers as problem solving stations**

In the case of many Indian hospitals, pharmacists contributed towards patient compliance through prescribers for simplification of drug regimens. Patient counseling enabled the pharmacist to identify or understand the usual medication habits of patients and their knowledge regarding drug therapy. In some cases, patients found it difficult to swallow big tablets like paracetamol 650 mg tablets and certain antibiotics. The pharmacists could easily suggest solutions for such issues.

At the counseling centers, pharmacists, through one-to-one talk and discussion, ensure that the patient understands both directions and the need to follow them. Patients are told about the adverse drug effects which can cause considerable inconvenience to them and explain what remedial action should be taken if such adverse effects occur (e.g. Co-trimoxazole). Patients are also educated about the foods or drugs that are to be avoided while taking the prescribed medicine (e.g. avoiding alcohol while taking metronidazole or avoiding cheese, yeast, etc. when MAO inhibitor drugs are taken). Clinically significant interactions alone are mentioned to the patients without unduly alarming them. Pharmacists in hospital and community pharmacies quite often provide written materials and audiovisual demonstrations including computer aided programs as a part of counseling activities.

### **Focus points in patient counseling**

Practicing pharmacists in India come in contact with more patients than any other health care professionals. The number of pharmacists to deliver the health care needs is quite promising in the country where, about 7 pharmacists per 1,00,000 population are currently available. This is against the average of 3.4 in the world<sup>5</sup>. The main objective of patient counseling is to provide information about the drug as per the prescription and then motivate the patient to adhere on the treatment. Counseling helps to improve the quality of pharmaceutical service and builds up the confidence of patients, which in turn increases motivation in the community to receive care services and to accept therapy. Like other parts of the world, in the past, pharmacy professionals in the country were against the concept of educating patients regarding their medicines. They believed that if patients are educated about their medications that can promote self medication and other hazards. Now there is no place for such concepts in the Indian health care sector.

The main focus point of patient counseling in India, like other parts of the world, is to educate the patient about the prescribed medicines and then motivate them to comply with the treatment and related aspects. It helps the patient to take the medication in a manner that is most likely to achieve the desired therapeutic response. The changing needs of the patient are also given due weightage. The counseling pharmacists uphold the principle that knowledge is power and great power never comes without responsibility.

The hospital pharmacists get many opportunities for patient counseling in the hospital from admission to discharge and afterwards in the out-patient clinics and dispensaries. They have the advantage of access to a lot of information about the patient like the disease, current therapy and home circumstances. Moreover, they get the opportunity to approach the counseling in a more formal manner than the community pharmacists. The hospital pharmacists are often in an advantageous position compared to their counterparts in the community set up in matters relating to the availability and choice of space for counseling, facilities like reference books, etc., for making the service efficient. Hospital pharmacists are also often subject to pressure and time constraints. This is more in the case of hospital pharmacies attached to private hospitals. In some hospitals, the pharmacists screen the patients once admitted and identify those who need counseling on a priority. In general, the Indian

patients want basic information about the disease state being treated, duration of treatment, cost, availability in the market, drug interactions and side effects in counseling session.

The sale of medicines from the community pharmacy is based on a direct request for a named medicine or a request for advice on the treatment of a symptom of minor ailment by a patient. This gives an exclusive opportunity for the Indian community pharmacists to initiate counseling as a part of sales of medicines. Community pharmacists alone get the chance to know about the OTC medicine practice of patients. However, compared to hospital pharmacists, the Indian community pharmacists are still weak in properly utilising the opportunity they get for providing counseling both in active and passive ways. Some times (about 10 %) the patients or their relatives appear not interested in spending additional time in the pharmacy for information about their medicines. Computer aided counseling system is not yet popularised in the country.

### **Problems and issues in Indian situation**

The important factors adversely affecting counseling in India include busy pharmacies, lack of time, non availability of suitable counseling area and absence of training in skills like communication and interview techniques. The benefits of patient counseling promises not only improvement in the quality of life for patients but enriches the profession of pharmacy. The pharmacists give preference to provide counseling to specialized patient population such as uneducated patients with specialized dosage forms like insulin injections, insulin pens, inhalers, rotahalers, spacers, suppositories and pessaries. Both in the hospital and community set ups, pharmacists are often taking certain steps to make counseling more fruitful and effective (see table 3).

Compared to developed countries, patient compliance is not satisfactory in India. On an average, compliance is less than 50 %. Education and financial problems are the important factors contributing to the issue. More than 70 per cent of the Indian population live in the villages, where compliance is a major health problem. Compliance is more among the educated middle class and upper class families. Patients from poor families are less compliant to medication mainly because of money. However, in many cases where medicines are supplied free of cost from hospitals, compliance is not good. Illiteracy, poor socioeconomic status and poor

knowledge about the disease and its treatment are found contributing negatively to compliance. Hospital pharmacies in general are doing better services in the area of patient education in the country. The medical insurance schemes are yet to be popularised in the country. It retains the unaffordable population as such facilities are lacking in the case of non communicable diseases like diabetes, hypertension or asthma. It also contributes for poor compliance as the patients are too poor to buy the medicines. Due to lack of examination and diagnosis. It also helps in many ways to

improve the quality of healthcare system with better patient care and therapeutic outcomes. Indian hospitals are fully aware of the importance of patient counseling and drug unaffordable in the case of medicines. Though government support and assistances are available for the treatment and prevention of communicable diseases, information services. With the introduction of Pharm.D program by the end of 2008, one can expect a bright future for patient counseling in India in the very near future.

**Figure 1: First patient counselling center in Medical College, Trivandrum, when started near the premises of the community pharmacy of the department of pharmacy practice in 1996.**



proper job avenues, postgraduate pharmacists are found reluctant to take up the jobs in community and hospital pharmacies<sup>9</sup>. The financial constrains of Indian community pharmacies often make them unaffordable to utilise the services of highly qualified pharmacists.

#### **CONCLUSION**

The concept of patient counseling is getting popularised in India during the last ten years. Pharmacists in many parts of the country started providing patient counseling with the objective of improving patient compliance. Patient counseling by pharmacists also enabled the doctors to spend more time on patient

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**Figure 2: The counselling center in 1997 with separate cabins and library facilities working on round the clock basis. Patients take their dispensed medicines to the center for proper advice and information. It also helps to detect and avoid medication errors at the prescription or dispensing centers**



**Table No. 1: Factors helped for the genesis of patient counselling in India**

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| Sl. no | Factors / Events   |
|--------|--|
| 1.     | Starting of M. Pharm, Hospital Pharmacy, in Delhi University in 1982 by Dr. B.D.Miglani, incorporating clinical and community pharmacy.  |
| 2.     | Starting of the first department of Pharmacy Practice ( Hospital and Clinical Pharmacy) in India at Govt. Medical College, Trivandrum, in 1992 by K.G.Revikumar.                     |
| 3.     | Education Regulations (ER) 1991 of the Pharmacy Council of India for D.Pharm course incorporating the principles of hospital, clinical and community pharmacy.                       |
| 4.     | Introduction of one year post graduate diploma in clinical pharmacy at CMC, Vellore, in 1995- 96 by Ms Chandra who was trained in UK.  |
| 5.     | Starting of the first independent patient counselling center in Medical College Hospital, Trivandrum, in 1996, attached to the department of Hospital and Clinical Pharmacy Services |
| 6.     | Starting of M.Pharm, Pharmacy Practice, programs and its popularisation in the country during 1997-2002 period.  |
| 7.     | Revised Pharmacist Oath adopted by Pharmacy Council of India in 1999.  |
| 8.     | Gazette notification to start Pharm.D by Health Ministry of India in May 2008 .  |

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**Table No. 2: Some of the early Institutions which initiated Masters program in Pharmacy Practice**

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| <b>Sl.no</b> | <b>Name of Institution and year of starting</b>   |
|--------------|---|
| 1.           | Delhi College of Pharmacy (Delhi University) 1982                                       |
| 2.           | JSS College of Pharmacy, Mysore 1996- 97  |
| 3.           | JSS College of Pharmacy, Ooty 1997  |
| 4.           | K.M. College of Pharmacy, Madurai 1997  |
| 5.           | Periyar College of Pharmacy, Trichy 1998  |
| 6.           | College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore 1998 |
| 7.           | KLE College of Pharmacy, Belgaum 1999.  |
| 8.           | Annamalai University, Chidambaram. 2001   |
| 9.           | Al-Ameen College of Pharmacy, Bangalore 2001  |
| 10.          | Govt. Medical College, Trivandrum 2001  |
| 11.          | College of Pharmaceutical Sciences, Manipal 2001  |
| 12.          | The National Institute of Pharmaceutical Education and Research(NIPER), Mohali 2003     |
| 13.          | Visveswarapura Institute of Pharmaceutical Sciences, Bangalore 2003                     |
| 14.          | The Vinayaka Mission's College of Pharmacy, Salem 2003                                  |
| 15.          | Sri Ramachandra college of Pharmacy, Chennai 2003                                       |
| 16.          | KMCH College of Pharmacy, Coimbatore 2003.  |

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**Table No: 3 Factors needed for effective counselling in Indian scenario**

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1. An area free from distortions and suitable for face to face discussions.
  2. Providing information in a concrete and simple manner.
  3. Avoiding medical terminologies and provide reasons for advise and cautions.
  4. Friendly behaviour and approach to the patient.
  5. Giving the patient chance and opportunity to ask questions related to their problems.
  6. Developing a trustworthy relationship with the patient.
  7. Developing a positive attitude in the patient.
  8. Providing required information about the disease and medicines.
  9. Suggesting changes in life style of patient, explaining reasons.
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## Role of Community Pharmacist in the Care of the Elderly

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### Abstract

One of the world's striking trends that have been widely recognized is the aging of its population. The pharmaceutical care of the elderly population is of utmost concern in the westernized countries. Even in India, where the average life expectancy is 62.5 years, the aging population is growing. The number of elderly women at any point of time is reported to be more than the number of elderly men. With the advancement of science and medicine, life span and productive life of an individual has greatly increased. Added to this is the advances made by the pharma industry in providing affordable modern drugs to control the different diseases. All these factors have contributed to the rise in the number and percentage of elderly population all over the world and even in India. Elderly are more likely to experience drug related problems than any other age groups and also the biggest prescription users (40%) than any other group in the community. Hence, it is necessary and essential to elucidate the role of community pharmacist in the pharmaceutical care of elderly. Community pharmacist should possess certain basic skills, relearn basic pharmacy practice skills, apply the skills for elderly care and carry out the preventive care, and also develop a rational and feasible pharmaceutical care plan (PCP) for the elderly care. As such, community pharmacists therefore can implement quite a few aspects of PCP in India and give benefit of their knowledge to the patients at large.

**Key words:** Community pharmacist, pharmaceutical care plan, elderly care, geriatric population, non-compliance, quality of life.

### INTRODUCTION

One of the world's striking trends that have been widely recognized is the aging of its population. In U.S., this phenomenon is widely known as the aging of the "Baby Boomers". 'Baby boomers' is the group of post World War II children, who had grown, had their careers and now retired and living as elderly people. Almost 13 % of the U.S population (35 million) is of the age of 65 years and above. This population is expected to increase to 20% (about 70 million) by the year 2020. In the period 2010 - 2030, the population of 65 years and older is expected to grow by 75% to over 70 million. The growth of population among the 'oldest of the old' i.e. 85 years of age and above is of great public concern. During 1995 - 2010, this population is expected to grow by 56 % as compared with 13 % growth of the population aged 65 - 84. This means that, a large share of the elderly population will be over 85 by the year 2020. Even in India, where the average life expectancy is 62.5 years, the aging population is growing. There are about 1.5 million People in India, living close to 100 years of age and about

8 million living between 75 - 85 years of age, and are growing at double the world average of 4.4 % every year. The number of elderly women at any point of time is reported to be more than the number of elderly men. Life span and productive life of an individual has now greatly increased due to the advancement of science and medicine. With eradication of some of the deadly diseases like polio, small pox, measles, diphtheria and good control over TB, malaria and leprosy; life span in India has certainly increased. Added to this is the advances made by our pharma industry in providing affordable modern drugs to control hypertension, diabetes, asthma and other chronic diseases has helped millions in our country to extend the life span. All these factors have contributed to the rise in the number and percentage of elderly population all over the world and even in India.

### Current health and medication problems with the elderly

Although there are many age related health problems with the elderly, some problems are common with the geriatric population, such as

- Hypertension
- Myocardial infarct (MI)

- Classical chest pain
- Peripheral vascular disorders
- Chronic stasis ulcers
- Deep vein thrombosis
- Chronic illnesses and conditions such as diabetes, arthritis, cardiovascular disorders, dementia, etc.

Accompanied by the above problems are also secondary disorders such as

- Urinary and fecal incontinence
- Sleep disturbances
- Anxiety followed by depression
- Disorders of GIT
- Elderly are also more prone to influenza and pneumonia

Their medication problems are also linked to their health problems. Elderly are more likely to experience drug or medication related problems than any other age groups. Elderly are the biggest prescription users (40%) than any other group in the community. It is often said that “20% elderly population in a community gives 80% prescription business to retail pharmacy”. Other striking facts about the use of medicines by elderly and the problems arising out of it are

- Nearly 80% of the elderly receive inappropriate therapy
- Over treatment is often prescribed
- Elders are more likely to experience drug related adverse events (ADEs)
- By one estimate, nearly 36% of all the ADEs happen with the elderly
- Out of these 36% ADEs, 28% require hospitalization
- Non compliance is another big problem with the elderly
- Often, non-compliance of the medication regimen leads to sever complications leading to hospitalization
- Nearly 11% of the non-compliance cases among the old results in hospitalization
- The prescription use by the elders increases with age. For example, between 65-69 years old senior citizens have 13% prescriptions per year, while those between 70-80 years of age have 15% prescriptions per year.
- Nearly 82% of the elderly take atleast one drug per day for some disorder or the other.

Thus, there is a big challenge and opportunity for a community pharmacist to address these drug related problems of the elderly and improve their quality of life.

#### **Role of community pharmacist in elderly care**

Every community pharmacist is most likely to come in contact with an elderly patient or customer. In some communities, this contact may be more frequent than in

other communities. For example, if there is a nursing home nearby or a colony of retired elderly people or in a well to do community where joint families live, these contacts are bound to be frequent. It is therefore necessary that a community pharmacist should be familiar with the tasks that have to be performed for the care of the elderly. But before he/she actually starts taking responsibility of the elderly, he/she has to learn some foundation skills in order to be ready to help the elderly.

a) Foundation or Basic skills to be acquired by a community pharmacist can be listed as follows

- First of all, he/she must display respect and compassion for the elderly
- Learn to use appropriate and cognitive techniques in interaction with geriatric patients, their families, their care takers and their health care professionals
- Take personal responsibility for an elderly patient and present yourself as assertive professional
- Learn to communicate with the elderly in the language and manner by which they will understand clearly
- Write down the important instructions for them in simple and clear language
- Demonstrate ethical conduct in all activities related to elderly. For example, do not ridicule them or laugh at their misunderstanding.

b) Relearn basic Pharmacy Practice skills:

To do this, a community pharmacist must do the following-

- Understand major principles of gerontology and geriatrics
- Design and execute investigations of geriatric pharmacy practice
- If possible, attend a short term geriatric residency pharmacy practice program in a nearby hospital
- Learn to draw an appropriate pharmaceutical care plan (PCP), with other healthcare professionals and/or other inter-disciplinary or multi-disciplinary teams
- Work harmoniously with these teams
- Understand the alternate care settings for geriatric patients where they can receive pharmaceutical care, like physiotherapy center or a yoga center where they can be taught simple exercises of yoga or breathing
- Understand and learn the use of various assistive devices for the elderly like wheel chairs, trolley support walking, supportive neck and waist belts,

Neck caps etc.

And finally,

- Be in touch with national and local organizations doing work in geriatric care
- Be upto date with current geriatric literature and net
- Accept evaluation of your work through peer review or through a professional organization

c) Applying the above skills for elderly care:

After having acquired these basic skills and positioning the pharmacy practice skills in place, a community pharmacist can now go ahead with applying these skills for elderly care. What are some of his tasks that he has to do for elderly care? Here are some of the tasks that he has to do to practice elderly care:

- First of all, he has to identify the seniors in his community who may have high risk for medication related problems
- He has to formulate potential solutions to resolve and prevent these medication related problems
- Provide ongoing medication therapy monitoring and assessment to the elderly patients
- Obtain detailed medication histories of the elderly patients by interviews to know their medication related problems
- Apply knowledge of geriatric pharmacotherapy to care for older patients and make the recommendations for appropriate, effective and safe medication therapy (remember older patients are often over-prescribed).
- Engage in verbal and written communications with elderly patients and also with other healthcare professionals
- Develop and demonstrate sensitivity to social and psychological aspects of aging process to understand their impact on medication use. For example, older people often feel that the drugs are not doing any better for them, then why to take so many drugs. A community pharmacist has to impress on them that the drugs are indeed working for better and revive their faith in the medicines
- A community pharmacist also has to observe, understand and appreciate the medication use process in different settings of elderly care
- A community pharmacist also has to understand the scope of pharmacy services (administrative and clinical) needed for elderly patients and develop first

hand knowledge for providing such services.

- And ofcourse, he has to interact on regular basis with other healthcare and social service professionals (and also with non-healthcare professionals like clergy, social workers in the hospitals) in planning and providing care for the elderly.
- He also has the responsibility to explain the economic and financial aspects of providing pharmacy services to the elderly or their kins who are close to them.

#### **Preventive care for the elderly**

Perhaps, the best contribution that a community pharmacist can do in his setting is to give preventive care for the elderly. It may not be possible for many community pharmacists, especially in India, to apply the skills stated above for the elderly care. Many may not be or even come in contact with other healthcare professionals and work out a combined or collaborative program for elderly care. But atleast they can give preventive care to help elderly patients in their community. This will not only prevent mishaps with the elderly, but also prevent some emergency situations. Also it will help to prevent adverse drug events (ADEs), medication errors and problems arising out of self medication among elderly.

Some of the guidelines for preventive care are as follows:

- Teach the elderly proper use of accessories like walking stick, rolling walker, neck collars, waist support belts etc
- Also teach them how to prevent falls in home and in surroundings. If possible visit their homes and inspect their bathrooms and toilet blocks to see if proper supporting bars/handles are installed
- Regularly check weights of the elderly and assess weight gain or loss
- Take medication review of all their prescribed drugs and other auxiliaries like vitamins, dietary supplements, herbal medicines that they take on their own.
- Monitor compliance of medication
- In your setting, set up screening program for the elderly for the following
  - Vision Screening
  - Screening for hearing problems
  - Screening for cognitive impairment (i.e. mental perception, memory, judgement, reasoning etc)
  - Screen for urinary incontinence
  - Screen for increased risk from fall in home or outside

- Screen for blood pressure
- Screen for diabetes and for control of diabetes
- Screen for dementia
- Screen for depression
- Screen for height and weight and assess BMI
- Screen for osteoporosis by BMD test. Other high end screening can be done with the help of a local polyclinic
- Oral health screening
- Colorectal cancer screening
- Mammography for breast cancer
- Cervical cancer screening
- Prostate cancer screening
- Lipid profile screening

Besides these, a community pharmacist must also set up educational programs for the elderly through distribution of simple medical literature on hypertension, diabetes, asthma, osteoporosis etc. Set-up lectures by some experts, film shows, VCD programs in a community hall. These educational programs can be focused on various topics such as appropriate medication use, rational use of drugs, prevention of medication errors, disease prevention and various topics on nutrition and diet etc. The best place to start such educational programs is the senior citizen's clubs, where you can get a captive audience. Community pharmacists should therefore develop a good rapport with such clubs and organizations of the elderly and participate in their activities on regular basis.

#### **Pharmaceutical care for the elderly**

Pharmaceutical care has been well defined in many articles as "Responsible provision of drug therapy for the purpose of achieving definite outcomes that improves a patient's quality of life". Community pharmacists have an excellent opportunity to provide pharmaceutical care and services to the elderly in their settings. There is also ample evidence that pharmaceutical care can benefit the elderly patients. However, the community pharmacists must have a pharmaceutical care plan (PCP) in their hands which aims to communicate, promote compliance and concordance with treatment (that the elderly are receiving) and achieve specified therapeutic outcomes. PCP has great potential to not only reduce drug related problems of the elderly, but to improve their quality of life and overall reduce the expenditure on drugs. The clinical skills of the pharmacists have to be used to manage the medication therapy of the elderly. This will rationalize the use of human resources in a community healthcare team and reduce the work load of the general practitioners (GP) in the community.

The next big question is how to develop a rational and feasible pharmaceutical care plan (PCP)? Following are some steps that can be taken to develop such a PCP:

- First of all, establish a good relationship with the patient and his doctor
- Collect relevant information on patient like disease state, drugs that he is receiving, clinical tests data etc. All this has to be done by working with his GP and the patient himself
- Identify drug related (potential) problems among the drugs he is receiving. Prioritise them in declining order, with the most likely first on the list
- Some of the drug related problems can be
  - Failure to receive the drug by the patient
  - Untreated indication
  - Improper drug selection
  - Not receiving proper dosage
  - May be even receiving an overdose of the drug
  - Adverse drug reaction due the medication that the patient is receiving
  - Drug-Drug interactions (DDI) from among the drugs written in the prescription for which there is no indication
- Establish therapeutic goals for each drug related problem
- Identify feasible alternative treatment, even with herbal medicines
- Select the best pharmaceutical solution, i.e. best possible drug, best suitable formulation of the drug and the best suitable dose
- Finally, get an agreement with the GP of the patient and the patient himself
- Implement and monitor the plan
- Follow up the plan and measure the outcomes
- Continue to update the PCP, with the patient's GP and study the outcome.

The community pharmacist will have to educate the patients and their caretakers about the PCP and the medicines that are recommended. He will also have to assist the patients and the caretakers about the need of compliance and provide them with compliance aids such as dose boxes, reminder charts and even send them SMS at appropriate times to ensure compliance. He should give his contact numbers and arrange for his personal visits to patients' home. The outcome can be measured by

- Clinical parameters like measurement of blood pressure, fasting blood sugar, total cholesterol etc. In chronic illness, measurement of creatinine and blood Urea can be done

- Other simpler methods are, patients' own assessment of well being their role in the therapy
- Correct response of patient to the questions asked about the therapy.

Although pharmaceutical care plan is a new concept in India, some of the aspects of PCP can easily be followed by a community or hospital pharmacist are information about the patients, indications, medicines that he is receiving, possible drug-drug interactions within his prescribed drugs, and most important of all, the over prescribed drugs and unnecessary drugs. Compliance is a big problem in India and community pharmacists can play a big role here. Most of the failures of positive therapeutic outcomes arise from non-compliance form India. Community pharmacists therefore can implement quite a few aspects of PCP in India and give benefit of their knowledge to the patients at large.

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## Pharmacist Mediated Assessment of Medication Knowledge and Counseling to Depressive Disorder Patients in Tertiary Care Hospital

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### Abstract

Medication knowledge is an important contributor for medication adherence which in turn improves therapeutic outcome. To assess the patient's knowledge on antidepressants and impact of pharmacist mediated counseling on their medication knowledge, patient's medication knowledge was assessed by administering medication knowledge assessment questionnaire. First assessment was considered as baseline assessment. Patients were counseled based on their knowledge on antidepressants. They were advised to attend two follow up sessions with an interval of one-month, during which they were administered with same questionnaire to reassess their medication knowledge and impact of pharmacist mediated counseling on their medication knowledge. The average medication knowledge score at baseline, first follow up and second follow up was 4.590, 6.431 and 7.318 respectively with statistically significant difference ( $p < 0.01$ ). There was a mean increase of 1.886 and 2.705 from baseline to first follow up and second follow up, and a mean increase of 1.841 from first follow up to second follow up, with statistically significant difference ( $p < 0.01$ ). The result shows the effectiveness of medication counseling by a pharmacist. Medication counseling done by pharmacist has significant impact on patient's knowledge. Assessment of medication knowledge in patients may influence their medication adherence, though it may not necessarily result in better clinical outcome.

### INTRODUCTION

Medication knowledge is the range of information that patients possess about the medications. It includes information about the name of the drug, indication, dose, dosage regimen, adverse effects, precautions to be taken during treatment, contraindications and storage conditions. Patient education and counseling is defined as a combination of teaching activities that focus on keeping patients' informed about their health condition, treatment plans, medication therapy and self care management to facilitate changes in behavior for improvement and maintenance of health.<sup>1</sup> Patient education aims to provide clinical information to patients with the goal of increasing understanding and encouraging health promoting behavior.<sup>2</sup> Patient education is the most important variable affecting treatment compliance. Faulty comprehension has been reported to contribute to some 2/3<sup>rd</sup> of compliance

problems. The basic assumption underlying the hypothesized value of patient education is that, an informed and motivated patient is more likely to be compliant if he understands his drug regimen.<sup>3</sup> According to SHPA (Society of Hospital Pharmacists of Australia) association, pharmacists have the responsibility to provide sufficient information and counseling to enable patients and/or their caretakers to achieve informed and judicious use of their medicines.<sup>4</sup> The role of pharmacist in the medical field has recently grown well beyond dispensing function and expanded to clinical trials, health economics and patient education.<sup>5</sup> Patient compliance with medication can be expected to significantly improve, once patients are made completely aware of the importance of diligently adhering to their prescribed regimens. Pharmacist, thus providing the information on prescribed drugs to patients, and stressing the importance of following the prescribed regimen, plays a central role in combating patient non-compliance.<sup>6</sup> The specialized skills of clinical

pharmacists have proved to be beneficial for improving treatment outcomes. Because of their skills in identifying drug interactions, their excellent position of direct contacts and trust by patients, pharmacist can thus help patients remove evident adherence barriers and incorporate interventions into the care of their patients.<sup>7</sup> Educating patients about antidepressants is necessary since it is the patient who is taking the medications. Treatment adherence is more likely when the clinician is open and flexible rather than authoritarian. Most treatment issues can and should be negotiated between the clinician and the patient, and the patient must be an active participant in his/her treatment decisions.<sup>8</sup>

#### **Aim of the study**

The primary aim of this study was to assess the patient's knowledge on antidepressants and the impact of clinical pharmacist mediated counseling on their medication knowledge.

#### **MATERIALS AND METHODS**

This study was approved by the Institutional Ethics Committee of JNMC of the KLES College of Pharmacy. Patients attending psychiatry OPD of KLE'S Hospital during the period from June 2007 to December 2007 were included in the study. Inclusion criteria were, all patients suffering from depressive disorder who were 18 years of age or older, Patients willing to participate, Patients taking antidepressants for at least last 3 months. An exclusion criterion was patients having other medical or psychiatric co-morbidities. Demographic data was obtained from all the patients. A total of 53 patients were enrolled into the study on their visit to the hospital and the study duration was 9 months.

#### **Counseling sessions and medication knowledge assessment**

Upon enrollment, patients were given a pre-test to evaluate their medication knowledge, using medication knowledge assessment questionnaire. Except for first question (which is to name the drug) in the medication knowledge assessment questionnaire, there were four responses expected for each question. Each response was assigned a score and then final scores were added to get the total score for that patient. Expected response and scores were: 1- answering the questions correctly; 0- not answering the questions correctly. Patients received medication counselling from the pharmacist based on their basic knowledge about antidepressants with the help of patient information leaflets.

#### **Medication counseling**

At the out patient department of psychiatry, counseling was performed in a separate chamber to ensure privacy.

Counseling sessions were designed so that all patients were counseled according to their individual understanding and attitude of their medication. Pharmacist explained about their disease, the antidepressants and its identification, indications, dose and regimen, duration of therapy, adverse effects, precautions and storage.

#### **Follow up visits**

All patients were followed up for two subsequent appointments, with an interval of one month, to reassess their medication knowledge.

#### **Statistical analysis**

Statistical analysis was carried out to study the significant difference between the follow-ups in medication knowledge by Mann Whitney U test, McNemar test and ANOVA test.

#### **RESULTS**

##### **Details of patients enrolled into the study**

Fifty three depressive patients were enrolled into the study, out of which 44 completed the study. Out of 44 patients, 22 (78.57%) out of 28 male patients and 22 (88%) out of 25 female patients have completed the study. Remaining nine patients did not turn up for the follow ups. Only those who completed the study were considered for the analysis.

##### **Educational status**

Out of 44 patients, 36 (81.81%) patients were literates and 8 (18.18%) patients were illiterates.

##### **Previous counseling underwent by patients**

Out of 44 patients, only 18 (40.90%) patients were counseled by psychiatrist and the remaining 26 (59.09%) patients had no previous counseling.

##### **Details of medication counseling by health professionals**

Out of 44 patients, 18 patients were counseled by psychiatrist. However, remaining 26 patients were neither counseled by psychiatrist nor by any other healthcare professionals particularly pharmacist.

##### **Assessment of medication knowledge Medication knowledge score (Score range: 0-10)**

The average medication knowledge scores were 4.59, 6.43 and 7.31 at baseline, first and second follow up respectively. Statistically significant difference ( $p < 0.01$ ) was observed when compared baseline with first and second follow ups scores. Moreover, medication knowledge score showed a trend of gradual increase at subsequent follow-ups (Table 2).

##### **Assessment of Medication Knowledge in male (Score range: 0-10)**

Medication knowledge of male patients was assessed as scores of 5.09, 6.59 and 7.54 at baseline, first and second

follow ups respectively. Statistically significant Difference ( $p < 0.01$ ) was observed in medication knowledge from baseline to first and second follow ups (Table 3).

#### **Assessment of Medication Knowledge in female (Score range: 0-10)**

Medication knowledge of female patients was assessed as scores of 4.09, 6.27 and 6.9 at baseline, first and second follow ups respectively. Statistically significant difference ( $p < 0.01$ ) was observed in medication knowledge from baseline to first follow up and second follow ups (Table 4).

#### **Comparison of medication knowledge between genders**

Medication knowledge scores between genders were found to be 1.00, 0.32 and 0.59 at baseline, first and second follow ups respectively (Table 5).

#### **Effect of educational status on medication knowledge**

Medication knowledge scores were compared between literates and illiterates at baseline, first follow up, and second follow up and found the difference of 1.18, 1.06 and 1.38 respectively. Both literates and illiterates showed statistically significant difference ( $p < 0.01$ ) from baseline to first and second follow ups, but literacy was not found to have any effect on medication knowledge of patients (Table 6).

#### **Distribution of knowledge**

Results at baseline assessment showed immense lack of medication knowledge among patients and the extent of education that is required. The distribution of medication knowledge in patients at base line, first follow up, and second follow up is shown in **Table 7**. Results showed a statistically significant difference ( $p < 0.01$ ) from baseline to first and second follow ups in patient's knowledge on different aspects of drug, except on drug administration and it's duration of treatment.

#### **DISCUSSION**

This preliminary initiative study was taken up because, in Indian hospitals, depressive patients do not attain counseling on antidepressant drugs.

#### **Details of patients enrolled into the study**

Out of 53 enrolled patients, 44 completed the study with remaining nine patients failing to turn up for the follow up due to unknown reasons. These drop-outs may be due to socioeconomic factors, patient's attitude and awareness of patients on psychiatric illness.

#### **Gender distribution**

The distribution of male and female patients was nearly equal (male 52.83% and female 47.16%) among the enrolled subjects. In the study conducted by Nathaniel MR et al.<sup>9</sup>, it was stated that, depression has a life time risk

of 10-15% in women and 5-12% in men but, it was not found in our study. The possible reason may be due to the fact that, females suffering from depression may not visit to psychiatrist due to social factors.

#### **Educational status**

Out of 44 patients, 36 were literates and remaining were illiterates. In India, most of the people think that they need not undergo treatment for depression since they feel it as a part of life, which may be because of their limited knowledge or awareness towards psychiatric illness particularly depression. This assumption is much higher in illiterates and could be one of the reasons for 18.81% of illiterate patients enrolling into the study.

#### **Previous counseling undergone by patients**

Only 40.90% of enrolled patients were counseled earlier for their antidepressant drugs. A survey to investigate the concerns, difficulties and needs of psychiatric patients in the community regarding their medication showed that, out of 83 people, 62% felt they had not been provided with adequate information about their medicines and 73% considered that having access to information would improve their confidence in their medicines.<sup>10</sup> In Indian healthcare settings this is often found to be the reason due to lack of information/or the negative attitude of patients and health care providers. Most of the patients do not ask for information about their treatment because they feel health care providers have less time for counseling. The findings of study are consistent with the study results carried out by Chavunduka D et al.<sup>11</sup> Henry NY et al.<sup>10</sup> concluded in their study that physician provide limited information to patients while prescribing antidepressants, often omitting critical information that may promote adherence. All the 18 patients were counseled by psychiatrist. Neither the pharmacist nor nurse was involved during the counseling process. This indicates the fact that, the community pharmacies are lagging behind in providing patient counseling services.

#### **Assessment of medication knowledge**

The study results show that the counseling sessions conducted by clinical pharmacist are able to produce a statistically significant improvement in medication knowledge in patients. Similar study was carried out by Kathleen MB et al.<sup>12</sup> in which they found intervention of pharmacist had higher scores in drug knowledge and belief than in non-intervention studies. Another study that was conducted by Ponnusankar S et al.<sup>13</sup> assessed the impact of medication counseling on patient's medication.

#### **Comparison of medication knowledge between genders**

Both the genders showed statistically significant

difference from baseline assessment. Medication knowledge score showed that, the impact of pharmacist provided medication counseling was same in both the gender. Medication knowledge score in females was found lower than in males, because of less education and busy household works which hinders them to understand the disease and its treatment. Since male patients spend most of their time outside, they get the opportunity to discuss about depression and antidepressants with their fellow mates.

#### **Effect of literacy on medication knowledge**

Both literates and illiterates showed improvement in their knowledge of antidepressants, but score was higher in literates compared to that of illiterates. Literates understand the disease and treatment much better than illiterates. Educational status helps them to understand and remember easily. This develops insight and positive attitude towards antidepressants. This may be the reason for differences in the medication knowledge score.

#### **Distribution of knowledge**

Majority of patients though literates, were not good at English language. This could be one of the reasons about their lack of awareness about antidepressants and their usage. John MD<sup>14</sup> described patient's attitude about medication and factors affecting medication compliance. Out of 148 psychiatric patients, 87 patients had positive attitude towards medication; 40 believed that their illness was biologically or chemically based; a large proportion believed their illness is due to situational factors, including stress (36) and family problems (18); 51 patients said they need medications to get better. The findings suggest that several relevant clinical, demographic and attitudinal variables may not be associated with compliance to medications. Patients fail to discuss their treatment with psychiatrist or pharmacist on antidepressants, their administration and actions, the duration of therapy, precautions, adverse effects and its management, storage of drugs. This may be due to the lack of information and/or negative attitude of patient.

#### **CONCLUSION**

The results obtained in our study have shown that medication counseling to depressive patients by a clinical pharmacist is effective in improving their understanding of specific drug therapy. The results show the effectiveness of medication counseling by a pharmacist using motivational interviewing techniques in improving insight, attitudes and medication knowledge in the short term. These gains were maintained throughout the study period. It cannot be assumed that these effects will be maintained for longer period by patients. The study

highlights an important role of the clinical pharmacist in medication counseling, advising on choice of therapy, assessing for occurrence of side effects in patients and advising thereof and along with other health professionals, helping to increase the quality of life in psychiatric patients. One of the limitations of this study was incomplete follow ups, in which nine patients could not be followed till the end of this study. Medication knowledge gained cannot assume to be maintained for longer period. Assessment of medication knowledge in patients may be good but may not necessarily result in better clinical outcome. Clinical outcome measurement can only be carried out during long term follow up of the patients. Since this was a preliminary study, it was not possible to measure the clinical outcome.

#### **Further direction**

As medication knowledge gained by patients cannot be assumed to be maintained for longer period, further follow up on medication counseling should be carried out. Future studies in this direction may incorporate the use of clinical outcome to assess the role of pharmacist in quality health care and effect of pharmacist mediated medication counseling on patients adherence to treatment.

#### **Practice implications**

Health setups in under developed countries may not have the facilities to assess patient's knowledge on antidepressants. However, pharmacist mediated medication counseling moderately helps to assess patients' medication knowledge. In this set up, provision of medication counseling by the pharmacist in an out patient department of psychiatry was well accepted and encouraged by the patients and psychiatric fraternity. Improved patient medication knowledge can lead to improved patient's insight and attitudes towards treatment. It has been proposed as an approach for directly addressing patient's knowledge and attitude concerning antidepressants.

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**Table 1 Demographic details of enrolled patients (n=44)**

| Characteristics                                    | Numbers |
|--|---------|
| Gender   |         |
| Male   | 22      |
| Female   | 22      |
| Educational status                                 |         |
| Literates  | 36      |
| Illiterates  | 8       |
| Previous counseling underwent by patients          |         |
| Yes  | 18      |
| No   | 26      |
| Medication counseling by health care professionals |         |
| Doctors/Psychiatrist                               | 18      |
| Pharmacist   | 0       |
| Nurse  | 0       |

**Table 2 Assessment of medication knowledge: (Score range: 0-10)**

| Average Baseline score | Average first follow up score | Average second follow up score | p Value |
|------------------------|-------------------------------|--------------------------------|---------|
| 4.59                   | 6.43                          | 7.31                           | p<0.01  |

**Table 3 Assessment of Medication Knowledge in male: (Score range: 0-10)**

| Average Baseline score | Average first follow up score | Average second follow up score | p Value |
|------------------------|-------------------------------|--------------------------------|---------|
| 5.09                   | 6.59                          | 7.54                           | p<0.01  |

**Table 4 Assessment of Medication Knowledge in female: (Score range: 0-10)**

| Average Baseline score | Average first follow up score | Average second follow up score | p Value |
|------------------------|-------------------------------|--------------------------------|---------|
| 4.09                   | 6.27                          | 6.95                           | p<0.01  |

**Table 5: Comparison of medication knowledge among gender**

| Gender     | Average Baseline score | Average first follow up score | Average second followup score |
|------------|------------------------|-------------------------------|-------------------------------|
| Male       | 5.09                   | 6.59                          | 7.54                          |
| Female     | 4.09                   | 6.27                          | 6.95                          |
| Difference | 1.00                   | 0.32                          | 0.59                          |

**Table 6 : Effect of educational status on medication knowledge:**

| Educational status | Average Base line score | Average first follow up score | Average second follow up score |
|--------------------|-------------------------|-------------------------------|--------------------------------|
| Literates          | 4.68                    | 6.56                          | 7.50                           |
| Illiterates        | 3.50                    | 5.50                          | 6.12                           |
| Difference         | 1.18                    | 1.06                          | 1.38                           |

**Table 7: Distribution of knowledge**

| Q No | Question   | Base Line   | First followup | Second follow up | Pvalue <than |
|------|--|-------------|----------------|------------------|--------------|
| 1    | What is the name of your drug?                         | 10 (22.72%) | 16 (36.36%)    | 25 (56.81%)      | 0.01         |
| 2    | What is this drug taken?                               | 25 (56.81%) | 40 (90.90%)    | 41 (93.18%)      | 0.01         |
| 3    | How does your drug work?                               | 02 (04.54%) | 07 (15.90%)    | 13 (29.54%)      | 0.01         |
| 4    | When do you take this drug?                            | 43 (97.72%) | 43 (97.72%)    | 43 (97.72%)      | 1.00         |
| 5    | How long do you have to take this drug?                | 03 (6.82%)  | 02 (04.54%)    | 04 (09.09%)      | 1.00         |
| 6    | What precautions do you take while taking these drugs? | 03 (6.82%)  | 20 (45.45%)    | 31 (70.45%)      | 0.01         |
| 7    | What are the adverse effects of your drug?             | 25 (56.81%) | 33 (75.00%)    | 37 (84.09%)      | 0.01         |
| 8    | What will do if you get any adverse effects?           | 22 (50.00%) | 37 (84.09%)    | 42 (95.45%)      | 0.01         |
| 9    | What will you do when you miss the dose?               | 27 (61.36%) | 38 (86.36%)    | 41 (93.18%)      | 0.01         |
| 10   | How do you store your drugs?                           | 36 (81.81%) | 41 (93.18%)    | 42 (95.45%)      | 0.01         |

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## Self Medication Pattern Among Elderly Patients of North India

### Public Hospital: A Hospital Based Questionnaire Appraisal

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#### Abstract

Self-medication is an economical choice of treatment for common self-limiting illnesses. Major problems related to this are wastage of resources, increased resistance of pathogens, and health hazards like adverse reaction. Elderly patients are more likely to self-medicate themselves in view of the multiplicity of disorder they may have. The aim of the study was to access the self-medication pattern among elderly inpatients in the medicine wards of the public hospital, Chandigarh. Prospective questionnaire-based interview covered 515 elderly patients. Any medication(s) taken without a prescription, prior (average of two and half months) to hospitalization were considered self-medication. Approximately 63% patients reported use of the non-prescription drugs/complementary medicine. Out of these 323 patients, 45.8% of the patients had used allopathic medications for treatment of their ailments without prescription or any medical advice. 18% of patients followed homeopathic and 30.3% patients were using ayurvedic medicines as self-medication. 6% patients used household remedies for self treatment. The number of patients who reported gastrointestinal disorders like gastric pain, acidity, diarrhea, and constipation as the most frequently self-treated symptom was 226. The other major reported illnesses include, fever in 110 and cough & cold in 95 patients. Analgesics/antipyretics like diclofenac, paracetamol and aspirin were the frequently used drugs. The drug for the treatment of acidity, flatulence and dyspepsia ranked second was antacids. On the basis of the feedback from 227 patients, the most probable reason for practicing self-medication was financial limitation. The prevalence of self-medication is quite high. In addition to allopathic drugs, a medicine from other systems of medicine was also commonly used for self-medication. Strict legislation regarding the accessibility of these drugs and education of the community on self-medication is essential for effective use of medicines is required.

#### INTRODUCTION

Self-medication is defined as “obtaining and consuming drugs without the advice of a physician either for diagnosis, prescription or surveillance of treatment”.<sup>1</sup> In developing countries, most of the illnesses are treated by self-medication.<sup>2</sup> According to WHO's definition<sup>3</sup>, self-medication is “the selection and use of medicines by individuals to treat self-recognized illnesses or symptoms”. Self-medication includes the use of nonprescription drugs and a range of different alternative medicines such as herbal remedies, food supplements, and traditional products. Home remedies (e.g., salt-water gargles for sore throat or garlic and honey for flu) can either be conceptualized as one form of self-medication or as part of nonmedical self-care. Self-medication with drugs is an economical choice of treatment for common

Self-limiting illnesses. Responsible self-medication can help, prevent and treat ailments that do not require medical consultation and reduce the pressure on medical services for the relief of minor ailments. These potential benefits seem to be of a particular interest in the financially less privileged countries with limited health resources. However, the practice of self medication can rather frequently have adverse effects, it can generate an additional burden on the system and increase counterproductive out of the pocket expenditure in already impoverished population.<sup>4</sup> Major problems related to self medication is wastage of resources, increased resistance of pathogens, and generally entails serious health hazards such as adverse reaction & prolonged suffering. Antimicrobial resistance is a current problem world wide particularly in developing countries where antibiotics are often available without a prescription.<sup>5</sup> As more medications are available and as the population of elderly continues to increase, a need

arises to monitor how elderly individuals use these agents.<sup>6</sup> Elderly living independently often self-medicate for common problems such as fever, mild pain, colds, allergies, indigestion/gas, constipation and insomnia. Self-treatment of common illnesses by people is common in developing countries. Common reasons cited for self-medication are inaccessibility of health care facilities, economic constraints and previous experience of illness.<sup>7,8</sup> Since, finding of self medication pattern and factors influencing this are lacking among elderly, the present study was carried out to access the self medication pattern among Indian elderly.

#### **METHOD**

A hospital-based survey was conducted for period of one year at the public hospital, in association with the Department of General Medicine. A sample of 535 elderly patients were selected randomly from four medicine wards. The inclusion criteria for the selection of patients was age above 60 yrs. Out of 535, 20 patients were excluded in accordance with the exclusion criteria like incomplete information, and some were unable to communicate. Each individual was given explanation about the purposes of research. A structured pre-tested questionnaire was used to collect the necessary information. The patients were interviewed and the investigator captured all the information. The questionnaire consisted of questions on demographic details, on the socioeconomic variables such as monthly income, type of medicine system, classes of medicines and name of a particular medicine. Any medication(s) taken without a prescription prior (ranging between 2-3 months) to hospitalization were considered self-medication. The results are based upon the data captured from 515 patients. The prevalence of self-medication was reported as percentages.

#### **RESULTS**

The number of males in the study was more than half of the total (62.5%). The average age ( $\pm$ SEM) of the patients was  $67.3 \pm 0.3$  yrs. Of the 515 patients, approximately 63% belonged to the age group of 60-69 yrs., 27% were in 70-79 yrs and only 10% were over 80 yrs of age. It was found that most of the patients lived with their family and more than half of the patients (63.3%) lived with their spouse. Most of the patients were financially dependent on their family members, but more than half of the patients (64.9%) had income of less than Rs. 2000/- per month. 386 patients had monthly income of less than Rs. 3500/-, while 123 patients had incomes in the range of Rs. 3500/- to Rs. 7000/- and 6

patients had incomes greater than Rs. 7000/- per month. 313 patients couldn't read and follow instructions written on the labels of drugs, but 202 patients could read the label and also follow the instructions provided. About a quarter of patients were working and others were retired. In this study, 323 out of 515 (62.7%) patients reported the use of non-prescription drugs/complementary medicine. Out of these 323 patients, 45.8% of the patients had used allopathic medications for treatment of their ailments without prescription or any medical advice. Apart from the allopathic medications, patients were reported using other system of medicine-17.6% patients followed homeopathic and 30.3% patients were using ayurvedic medicines. The remaining 20 patients reported the use of substances available at home for treatment of their minor illnesses.

The number of patients who reported gastrointestinal disorders like gastric pain, acidity, diarrhoea, and constipation, as the most frequently self-treated symptom was 226. The other major reported illnesses included fever in 110 and cough & cold in 95 patients (Table 1). It was noted that one patient reported multiple illness.

The analgesics and antipyretics were the most frequently used drugs. About 57% of the patients used a medicine for pain. The most commonly used analgesics/antipyretics were diclofenac, paracetamol and disprin. The subgroup of drugs for the treatment of acidity, flatulence and dyspepsia ranked second and was mainly made up of antacids; H-2 receptor antagonist and proton pump inhibitors. A cough and cold preparation was mainly combination product containing at least two of the following: analgesic-antipyretic drugs, antibiotics, antihistamines and decongestant and herbal extracts. Table 2 shows the profile of the medicines consumed without prescription. It was noted that one patient reported multiple use of medicines. Another 15 (4.6%) patients reported side effects of nonprescription drug use. The most probable reasons, on the basis of the feedback from the patients, for practicing self-medication were as follows:

1. Financial limitations (n=227)
2. Considered their ailment too minor for professional attention (n=203)
3. Easy availability of drugs (n=197)
4. Increased advertisement of the drugs (n=145)

#### **DISCUSSION**

Pharmaceutical advances have helped the community and patients with respect to disease prevention and management. However, without exception, most

Pharmaceutical products have the potential to cause adverse consequences of varying severity and frequency. In the last 10 years, many medicines that were originally 'prescription only' have now become available without prescription, either from pharmacies or other general retail outlets. The volume and value of these medicine sales have increased accordingly.<sup>9</sup> The easy availability of drugs pose risks to patients<sup>10</sup>; thus, it is important to understand patient's choices on allopathic medicine and complementary/alternative medications especially those used for self-medication. The reported extent of self medication practice ranges between 15-65%.<sup>2</sup> Consistent to this, majority of the patients (62.7%) in this study were taking atleast one medication for self medication which also matches with the results of other groups.<sup>11,12</sup> The most common illnesses (gastric pain, fever, cough and diarrhea) that led to self medication in this study were also reported in the findings from other countries.<sup>13</sup> Analgesics are generally well tolerated and effective when taken for brief periods of time and at recommended dosages. However, their long-term use, use of inappropriately high doses, or use by persons to whom drug is contraindicated may result in adverse effects, including gastrointestinal hemorrhage, cardiovascular toxicity, renal toxicity and hepatotoxicity. To reduce the risks of potential adverse effects from analgesic drug in elderly, the improvement in labels of drug and better education/counseling for patient is required. Improved labeling of analgesics may help consumers to distinguish common analgesic ingredients in a wide variety of preparations and facilitate informed decisions concerning the use of drugs.<sup>14</sup> In concordance with previous results<sup>2,15,16</sup>, this study has demonstrated that antimicrobials were commonly used for self-medication. A major problem with self-medication with antimicrobials is the emergence of human pathogen resistance. Antimicrobial resistance is a worldwide problem, particularly in developing countries where antibiotics are often available without a prescription.<sup>17</sup> The increase in self-care is due to a number of factors viz. socioeconomic factors, lifestyle, ready access to drugs, the increased potential to manage certain illnesses through self-care, public health and environmental factors, greater availability of medicinal products, and demographic and epidemiological factors.<sup>3,18</sup> The most common reason for practicing self medication as identified in this study on the basis of feedback from the elderly inpatients, was financial limitation. This leads to

the inability to afford professional medical care. The other reasons identified for not seeking medical advice was that the elderly patients considered their problems 'too minor' for healthcare professional advice, easy availability of drugs and increased advertisements of drugs.

The availability of potentially unsafe drugs has made self medication a risky proposition. A large majority of elderly were unaware of the adverse risks associated with concurrent use of pain medicines, alcohol and other drug use which was also confirmed in our findings.<sup>19</sup> This makes it necessary for all healthcare professional to intensify efforts to educate and advise the elderly patients to ensure safe and appropriate use of drugs.

The study had a few limitations. First, the results of this study are based on the retrospective self-reports which has its inherent problems (eg. Forgetfulness, reporting bias). Secondly, the results should be generalized with caution because the patients were inpatients

**Table 1: Frequency of the reported symptoms self-medication**

| Type of symptom      | Frequency <sup>2</sup> |
|----------------------|------------------------|
| Gastric pain/acidity | 126                    |
| Constipation         | 56                     |
| Diarrhea             | 44                     |
| Fever                | 110                    |
| Cough and cold       | 95                     |
| Back pain            | 47                     |
| Joint pain           | 38                     |
| Generalized Weakness | 32                     |
| Headache             | 25                     |
| Eye disease          | 23                     |
| Insomnia             | 11                     |
| Muscle pain          | 9                      |
| Tooth ache           | 7                      |
| Skin pruritis        | 7                      |
| Nausea, vomiting     | 5                      |

### CONCLUSIONS

The results indicate that self-medication is widespread among elderly. Although self-medication is difficult to eliminate, interventions can be made to discourage this practice and ensure safer usage of drugs, especially in the susceptible subsets of patients like elderly. The intervention will require better patient education of the Public and health professionals, and strong reinforcement, to avoid the irrational use of drugs. Strict legislation regarding the accessibility of these drugs by elderly may also be warranted.

**Table 2: Drugs Classes Used for Self Medication**

| Class                       | Frequency | Percentage |
|-----------------------------|-----------|------------|
| Analgesics/Antipyretics     | 184       | 57         |
| Antacids                    | 96        | 29.7       |
| Cough And Cold Preparations | 87        | 26.9       |
| Vitamins/nutrients          | 68        | 21         |
| Antibacterials              | 54        | 16.7       |
| Laxatives                   | 47        | 14.5       |
| Antidiarrhoeals             | 39        | 12         |
| Antihistaminics             | 24        | 7.4        |
| Sedatives/Hypnotics         | 8         | 2.4        |
| Skin cream                  | 7         | 2.1        |
| Iron tablet                 | 5         | 1.5        |
| Antiemetic                  | 5         | 1.5        |

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## Assessment of Antibiotic Use in Pediatric Patients at a Tertiary care Teaching Hospital

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### Abstract

Emergence of resistant bacterial pathogens has increased concerns about antibiotic prescribing patterns. The aim of the study was to assess the antibiotic use in pediatric patients. The study was carried out in a 500 bedded multi-speciality tertiary care teaching hospital at Coimbatore for the period of eight months from May 2007 to December 2007. During the study period, all inpatients of the pediatric ward that were prescribed with antibiotics were screened. The study result showed that there were a total of 214 (52.5%) cases prescribed with antibiotics. The major disorders for which antibiotics were prescribed included acute gastroenteritis (15%), lower respiratory tract infections, (14.5) upper respiratory tract infections (13.5%) and pyrexia of unknown origin (13.5%). In only 13.6% of the cases culture and sensitivity test was done and in 9.3% of the cases, micro-organisms were isolated. The organisms isolated were *Streptococcus pneumoniae* (3.7%), *Staphylococcus aureus* (1.9%), *Pseudomonas aeruginosa* (0.9%) and *E.coli* (2.8%). The most commonly prescribed antibiotic class was cephalosporins (68.2%). The most frequently prescribed antibiotic was cefuroxime (22.9%) and the commonly used antibiotic combination was cephalosporin with aminoglycoside (6.5%). The study result showed that ampicillin was the antibiotic used commonly to treat acute gastroenteritis (75%); cefuroxime for both lower respiratory tract infections (81.3%) and asthma (50%); amoxicillin/clavulanate potassium for both upper respiratory tract infections (41.4%) and pyrexia of unknown origin (34.5%); ceftriaxone/sulbactam for both acute otitis media and seizure disorder (69.2%) respectively.

**Key words:** Antibiotics, Organisms, Antibiotic use, Pediatrics

### INTRODUCTION

Emergence of resistant bacterial pathogens has increased concerns about antibiotic prescribing patterns<sup>1</sup>. During the last decennia, antibiotic resistance is on the rise<sup>2</sup>. This is mainly due to the abuse of broad-spectrum antibiotics in first-line treatment, or erroneous use (e.g. treatment of viral respiratory tract infections), use of multiple courses (e.g. cystic fibrosis patients) or prolonged duration of antibiotic treatment. The prevalence of more specialized pathologies requiring intensive antibiotic therapy or prolonged hospitalization, immunosuppressed conditions, invasive techniques put the children at high risk for opportunistic or nosocomial infections<sup>3</sup>. Healthcare professionals have a responsibility of creating a safe medication environment and reducing risk to a vulnerable pediatric population. Over prescribing not only cause non compliance and increased side effects, but also adds to the financial burden of patients<sup>4</sup>. To

overcome the above problems and to assure safe and cost effective therapy, antibiotic guidelines are required in a hospital setup. By definition, "Antibiotic guidelines are standard set of guidelines for the treatment of infectious diseases based on local culture sensitivity data." These guidelines help the physician to handle the antibiotics with caution and use them in the right dose and for the right duration only when definitely indicated. This will improve the quality of prescribing and may help in overcoming the problems associated with improper use of antibiotics.

### MATERIALS AND METHODS

#### Study site

The study was conducted in the department of Pediatrics at a 500-bedded multi-specialty medical institution; and one of the largest hospitals in Coimbatore. The reason for the selection of the department of pediatrics was that, the pilot study revealed more scope for the study in the department of pediatrics as the prevalence of antimicrobial prescription is more.

### **Study period**

The study was carried out for the period of eight months from May 2007 to December 2007.

### **Study design**

Prospective-Observational study

### **Patient selection**

All the patients who were prescribed with antibiotics in the Pediatric ward were included in the study. Only inpatients were included in the study. The outpatients and intensive care patients were excluded in the study.

### **Study approval**

The protocol of the study that includes the objectives and methodology was submitted to the Dean of the study hospital. The authorization from the Dean was procured on 5<sup>th</sup> May 2007 as per SRH/DEAN/F. 19/2007-2008. The author was permitted to utilize the hospital facilities to make a follow up of the prescriptions in the selected department.

### **Study material**

A specially designed data entry format was used to enter all patient's details like patient name, age, sex, weight, inpatient number, date of admission, date of discharge, reason for admission, past medical history, food habits, known allergies, previous ADRs, any surgical procedures done, vital signs like temperature, BP and pulse. Provision is given in the format to enter laboratory investigations, specimen collected, organisms identified, sensitivity to various antibiotics, diagnosis made, number of drugs prescribed and category of antibiotics prescribed.

### **Study procedure**

The study was carried out in three phases. A pilot study was carried out for a period of two weeks in the Department of Pediatrics to find the scope of the study in this department. All the antibiotic containing prescriptions were monitored to know the frequency and extent of antibiotic use and also for conditions in which it was prescribed. The study protocol was designed and the necessity of the study was explained to the chief pediatrician of the study hospital. The consent form from the hospital authority was obtained during this phase. Literatures, which support the study, were collected and were reviewed for study on importance of antibiotic prescribing patterns in pediatrics. A standard data entry format for collecting patient details was designed and, during the ward rounds the entire patient data with special reference to the antibiotic prescribed were recorded in the format. The details regarding the results obtained from the study, which were evaluated, were made as a report and were submitted to the concerned department along with the guidelines.

## **RESULTS AND DISCUSSION**

During the study period, a total of 408 patients were admitted in the pediatric ward. Out of which, 214 (52.5%) children were prescribed with antibiotics for the treatment of various disorders. Sixty (28%) of the study patients fall between the age group of =2 years <5 years, and between the age group of =5 years <12 years, there were 56 (26.2%) patients. In general, more patients were between the age group of 2 to 12 years. Similar studies conducted by Chkhaidze I (2006)<sup>5</sup> revealed that the incidence of infection is lowest in the age group up to 6 months. The duration of stay for maximum number of children (65.4%) were between 4 to 5 days, which is normally required to complete the recommended schedule of antibiotics. Similar study conducted by Ufer M et al in 2005 indicated that the mean treatment duration was directly proportional to the hospital stay<sup>6</sup>. The major reason for the admission was fever (72%) which most of the times is the major indicator for infection and requires antibiotic use. The other reasons for admission were cough (29.9%) and dyspnea (26.6%). Major disorders observed for which antibiotics prescribed in the department of pediatrics were acute gastroenteritis (15%), lower respiratory tract infections (14.5%), upper respiratory tract infections (13.5%), pyrexia of unknown origin (13.5%) and otitis media (6.1%) (Table 1). Other disorders include viral pyrexia, enteric fever, fits, and bronchiolitis. Similar studies conducted by Jonathan A Finkelstein in 2001 reported that otitis media accounted for the majority of antibiotic courses dispensed<sup>7</sup>. Out of 214 cases prescribed with antibiotics, only for 29 (13.6%) cases, culture and sensitivity test was done; and micro-organism was isolated in 20 (9.3%) cases (Table 2). As the sensitivity pattern studies reflect the major organism to be treated, it helps to choose the appropriate antibiotics resulting in appropriate antibiotic therapy. Of all the cases analyzed, 32.7% patients were prescribed with 3 drugs per prescription. 27.6% prescription contained 2 drugs and 17.3% prescription contained 4 drugs per prescription. The average number of drugs per prescription was 3.3. Majority of the patients were treated with single antibiotic (84.6%). Two antibiotics were prescribed in 11.2% cases and three antibiotics were prescribed in 3.7% cases. Only in one case (0.5%) four antibiotics were prescribed (Fig. 1). Even though antibiotic combination therapy may be effective as an initial approach to resistant organisms, it should be confirmed by sensitivity pattern studies. Various

categories of antibiotics prescribed were analyzed (Fig.2), which revealed that cephalosporins were prescribed widely in 146 (68.2%) prescriptions followed by penicillins in 68 (31.3%) prescriptions. Similar studies conducted by Sandra R Arnold in 1999 revealed that antibiotics from the penicillin class were the most frequently prescribed. Other categories of antibiotics prescribed include aminoglycosides (8.9%), macrolides (6.1%) fluoroquinolones (4.7%) and sulfonamide (0.5%). Similar studies conducted by Christopher J Stille et al in 2004 revealed that second generation macrolides use among children increased greatly, in contrast to the nationwide decrease in antibiotic use<sup>8</sup>. Cefuroxime was the most frequently prescribed antibiotic (Table 3). It was prescribed in 49 (22.9%) cases followed by ceftriaxone/sulbactam in 43 (20.1%) prescriptions, amoxicillin/clavulanate potassium in 36(16.8%) prescriptions, ampicillin in 30 (14%) prescriptions and ceftriaxone in 29 (13.5%) prescriptions respectively. Other commonly prescribed antibiotics were roxithromycin, gentamicin, and ceftriaxone/tazobactam. Antibiotic combinations commonly used (Fig.3) were found to be cephalosporin+ aminoglycoside (6.5%),cephalosporin+ macrolide(1.9%) and penicillin+

aminoglycoside (0.9%). Combination therapy as an approach to reducing bacterial resistance has potential, but additional studies are required to provide adequate support for its use. Of the 258 antibiotics administered, 203 (94.9%) were administered through IV route and 54 (25.2%) were administered through oral route. The study on the usage of antibiotics for various disorders revealed that ampicillin was the antibiotic used commonly to treat acute gastroenteritis (75%); cefuroxime for lower respiratory tract infections (81.3%) and asthma (50%); amoxicillin/clavulanate potassium for both upper respiratory tract infections (41.4%) and pyrexia of unknown origin (34.5%) and Ceftriaxone/Sulbactam for both acute otitis media and seizure disorder (69.2%) respectively (Table 4). Similar studies conducted by Robin E Huebner in 2003 revealed that cephalosporins were used most frequently to treat penicillin-resistant pneumococcal disease<sup>9</sup>. The other classes of drugs prescribed along with the antibiotics were also analyzed. The major classes of drugs prescribed were NSAIDs (69.2%), bronchodilators (26.6%), expecto-rants (21.5%), antidiarrheals (15%), and antihistamines (14.5%).

**Figure 1: Number of antibiotics prescribed per prescription (n=214)**

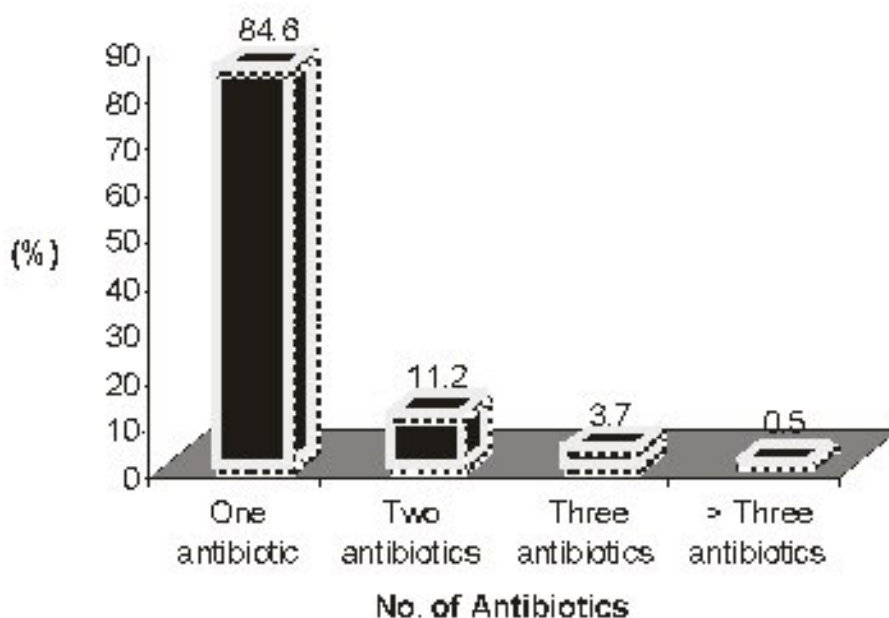


Figure 2: Various category of antibiotics prescribed (n=214)p

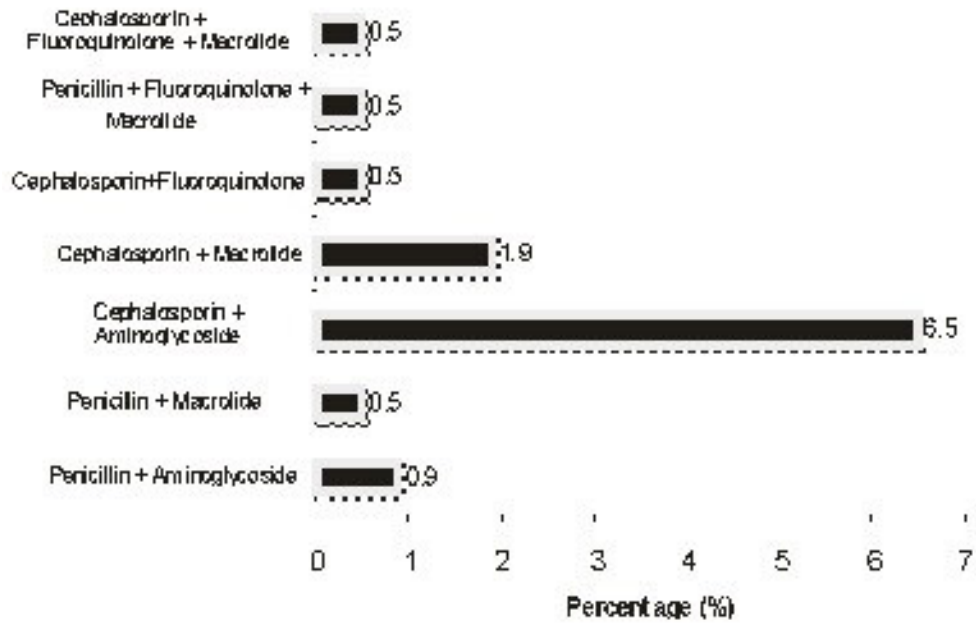
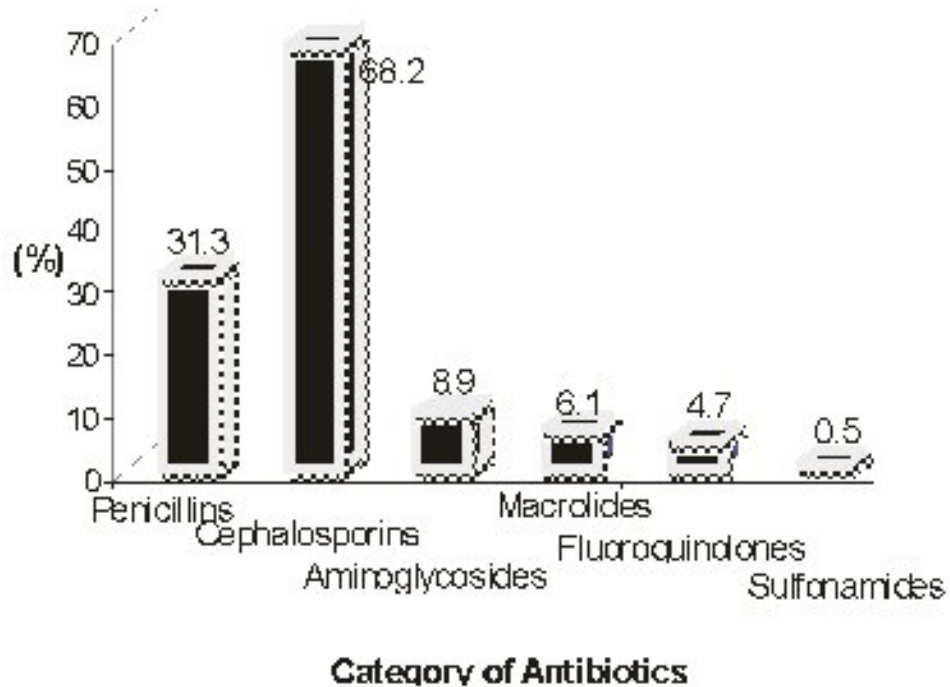


Figure 3: Antibiotic combinations used (n=214)



**Table No. 1: Various clinical conditions treated with antibiotics (n=214)**

| Disorders                          | No. of Patients | Percentage (%) |
|------------------------------------|-----------------|----------------|
| Acute enteric enteritis            | 32              | 15             |
| Lower respiratory tract infections | 71              | 34.5           |
| Upper respiratory tract infections | 29              | 13.5           |
| Acute otitis media                 | 13              | 6.1            |
| Etiocarditis                       | 6               | 2.8            |
| Pneumonia                          | 7               | 3.4            |
| Asthma                             | 19              | 9.4            |
| Enteric fever                      | 6               | 2.8            |
| Urinary tract infections           | 1               | 0.9            |
| Cellulitis                         | 1               | 0.9            |
| Appendicitis                       | 1               | 0.5            |
| Parasita of unknown origin         | 9               | 4.2            |
| Viral pyrexia                      | 6               | 2.8            |
| Seizure disorder                   | 13              | 6.1            |
| Tuberculosis                       | 1               | 0.5            |
| Bowel infection                    | 1               | 0.5            |
| Meningitis                         | 1               | 0.5            |
| Others                             | 6               | 2.8            |

**Table No. 2: Sensitivity Pattern Studies (n=214)p**

| ORGANISM                 | Sensitivity Pattern |             |            |                |             |                |             |            |            |           |               |          |            |              |                |              |              |                 |           |                |
|--------------------------|---------------------|-------------|------------|----------------|-------------|----------------|-------------|------------|------------|-----------|---------------|----------|------------|--------------|----------------|--------------|--------------|-----------------|-----------|----------------|
|                          | Penicillin          | Amoxicillin | Gentamicin | Nalidixic acid | Cloxacillin | Nalidixic acid | Ceftriaxone | Cefuroxime | Cefotaxime | Cefazolin | Ciprofloxacin | Imipenem | Cyfluthrin | Sparfloxacin | Clarithromycin | Erythromycin | Tetracycline | Chloramphenicol | Linezolid | Nitrofurantoin |
| <i>E. coli</i>           | 6                   | 6           | 7          | 6              | 6           | 7              | -           | 5          | -          | 3         | 6             | 5        | 6          | 7            | 6              | -            | 6            | 3               | -         | 7              |
| <i>Strep. Pneumoniae</i> | 8                   | 3           | 2          | 5              | 6           | 6              | 4           | 7          | 6          | 6         | 8             | 4        | 4          | 4            | 3              | 6            | 7            | 4               | 4         | -              |
| <i>Pseudomonas</i>       | 2                   | 2           | -          | 7              | 3           | -              | -           | -          | -          | 7         | 2             | 2        | 2          | 7            | 2              | -            | 7            | -               | -         | -              |
| <i>Staph. aureus</i>     | 7                   | 3           | 7          | 2              | 7           | 7              | 7           | 2          | 2          | 7         | 7             | 3        | 2          | 7            | 7              | 2            | 2            | -               | 2         | -              |

**Table No. 3: Break up of antibiotics prescribed (n=214)**

| Antibiotics                 | No. of Prescriptions | Percentage (%) |
|-----------------------------|----------------------|----------------|
| Amoxicillin                 | 01                   | 00.5           |
| Amoxicillin/pt. clavulanate | 36                   | 16.8           |
| Ampicillin                  | 30                   | 14.0           |
| Benzathine penicillin       | 01                   | 00.5           |
| Ceftriaxone                 | 29                   | 13.5           |
| Ceftriaxone/Sulbactam       | 43                   | 20.1           |
| Ceftriaxone/Levofloxacin    | 07                   | 03.3           |
| Cefuroxime                  | 19                   | 22.9           |
| Cefixime                    | 05                   | 02.3           |
| Cefixime                    | 04                   | 01.9           |
| Cefipime/Levofloxacin       | 02                   | 00.9           |
| Cefotaxime                  | 03                   | 01.4           |
| Cefotaxime/Sulbactam        | 01                   | 00.5           |
| Cefaclor                    | 01                   | 00.5           |
| Cefprozil                   | 01                   | 00.5           |
| Cefixim                     | 01                   | 00.5           |
| Gentamycin                  | 15                   | 07.0           |
| Amikacin                    | 02                   | 00.9           |
| Netilmicin                  | 01                   | 00.5           |
| Streptomycin                | 01                   | 00.5           |
| Clarithromycin              | 03                   | 01.4           |
| Roxithromycin               | 09                   | 04.2           |
| Azithromycin                | 01                   | 00.5           |
| Ofloxacin                   | 07                   | 03.3           |
| Ciprofloxacin               | 02                   | 00.9           |
| Sparfloxacin                | 01                   | 00.5           |
| Co-trimoxazole              | 01                   | 00.5           |

**Table No. 4: Major Disorders VS Antibiotics Prescribed**

| Disorder                           | Antibiotics prescribed   |
|------------------------------------|--|
| Acute gastroenteritis              | Ampicillin, Ofloxacin, amoxicillin-clavulanate potassium, ceftriaxone, cefixime  |
| Lower respiratory tract infections | Cefuroxime, cefixime, ceftriaxone/sulbactam, amoxicillin-clavulanate potassium, roxithromycin, cefepime  |
| Upper respiratory tract infections | amoxicillin-clavulanate potassium, ceftriaxone, cefepime, ceftriaxone/sulbactam, cefuroxime, roxithromycin   |
| Synusitis unknown origin           | Amoxicillin-clavulanate potassium, amoxicillin-clavulanate potassium-gentamycin, cefepime, ceftriaxone, ceftriaxone/gentamycin, amoxicillin-clarithromycin, gentamycin, ceftriaxone/sulbactam, ceftriaxone/tazobactam, cefuroxime, ciprofloxacin |
| Acute otitis media                 | Ceftriaxone/sulbactam, ceftriaxone/tazobactam, ceftriaxone, cefuroxime   |
| Seizure disorder                   | Ceftriaxone/sulbactam, ceftriaxone/tazobactam, ceftriaxone/gentamycin, ceftriaxone   |
| Asthma                             | Amoxicillin-clavulanate potassium, cefuroxime, clarithromycin, roxithromycin   |
| Enteric fever                      | Ceftriaxone, ceftriaxone/sulbactam, amoxicillin-clavulanate potassium  |
| Mononucleosis                      | Cefuroxime, cefuroxime/roxitromycin, amoxicillin-clavulanate potassium   |

As antibiotics share a very high percentage in any prescription, study on appropriate use of antibiotics and sensitivity pattern in the study hospital set up is to be conducted in periodic intervals. The study revealed that ampicillin was the antibiotic used widely to treat acute gastroenteritis; and cefuroxime for lower respiratory tract infections. When prescribing antibiotics, the knowledge on the organisms prevailing and the sensitivity pattern of antibiotics in the study hospital will help the health care professionals to select the appropriate one. Development of antibiotic policy for the study department is very much essential.

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## Evaluation of Drug Information Service provided by Clinical Pharmacy Department based on Provider and Enquirers' Perspective

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### Abstract

Drug Information service is an important role of clinical pharmacist and drug information service provision by clinical pharmacist is slowly being adopted in our country. There is a need to evaluate the quality of services provided by the drug information centers. This study was aimed for evaluating the services provided by a drug information center of a tertiary care hospital in South India. The quality of the service was evaluated based on providers as well as enquirers' perspective. Providers' perspective was evaluated based on a tool developed by DSE / WHO Seminar. Enquirers' perspective was evaluated by survey questionnaire. Evaluation results showed that both judgmental and non-judgmental queries had rating of very good or above. When enquirers' perspective was evaluated, around 70% of clinicians used services of the center and around 70% of the people felt that services were very good. 98% of surveyed physicians opined that there is a need for drug information center in the hospital. Evaluation of quality of service of drug information center based both on providers as well as enquirers' perspective showed that they were of good quality.

### INTRODUCTION

Drug information centers (DICs) provide mainly health-care professionals and general public with information about all aspects of drugs. Drug information may also be needed for academic or research purposes<sup>1</sup>. According to the Society of Hospital Pharmacist Australia (SHPA), among the different clinical pharmacy services provision of drug information is one of the most important services. The goal of clinical pharmacist involvement in the provision of drug information is to contribute to patient care and to optimize drug therapy. Clinical pharmacist involvement will help clinicians to understand about new drugs for which little information is available<sup>2</sup>. In the past, drugs were few in number and generally of low potency. However, in the present situation due to therapeutic explosion more than 60,000 formulations are available in the market<sup>3</sup>. Moreover, due to information explosion, vast availability of literature and lack of time; health care professionals are not in a position to update their knowledge. Though there are prescription and non-prescription drugs; the free availability of drugs, irrational drug use, iatrogenic diseases, antibiotic Resistance, adverse drug reactions and events are very common in India. These factors have resulted in an

Increasing demand for independent, unbiased information about drugs for a better patient care<sup>4</sup>. Rosemary Sharp, a missionary from UK, started first "Drug Information Center" in India at Christian Medical College, Vellore in early 1970's. This center provides information on drugs to doctors, nurses, pharmacists, and other staff like research personnel of various departments. The first officially recognized department of Hospital and Clinical Pharmacy Services in a government institution was started in Medical college Hospital, Thiruvananthapuram in November 1992 as a new department of College of Pharmaceutical Sciences<sup>5</sup>. In 1997, JSS Institutes of Mysore & Ooty started clinical pharmacy services along with drug information services. Because of the success of their clinical pharmacy activities, in 1998-99 many institutions in south India started clinical pharmacy services and drug information centers. Quality assurance of services provided by drug information center is one of the important tasks to be performed by personnel involved in the activity. Quality Assurance of the drug information center is aimed to identify the key areas of drug information practice and establish indicators for these key areas like structure, process and outcome. There is also a need to establish minimum acceptable levels of performance for these indicators and review performance against these

Indicators. As a result of this quality assurance process, there is scope for identifying opportunities for improvement. Quality of the service provided by the drug information center can be evaluated based on provider and enquirer's perspective to get the complete information. This approach avoids the one sided evaluation and thereby resulting in better appraisal of the services. The present study was aimed at evaluating drug information services of the author's institute from both providers and as well as enquirers' perspective for the period of 2006-07.

#### **METHODOLOGY**

The study was conducted in a hospital in South Indian state of Karnataka, which is a 1472 bedded tertiary care multi-specialty teaching hospital. The Pharmacy Practice department located in this hospital provides drug information to all health care professionals. The study period was between August 2006 and February 2007. The provider's perspective of the evaluation was carried out using suitably designed Quality assurance forms (Fig.1). These quality assurance forms were based on the guidelines developed in the DSE/WHO seminar on evaluating the quality and effectiveness of a drug information center.<sup>6</sup> In these guidelines, responses to queries have been categorized as judgmental and non-judgmental type. Based on the total number of judgmental and Non judgmental queries, sample size of the queries to be evaluated is fixed on the basis of anticipated proportion method. For Non Judgmental queries, the sample size was fixed as a minimum of 22. Therefore, 25 samples were fixed and equal number is fixed for Judgmental queries also. Therefore, total of 50 queries of 25 each of the judgmental and non-judgmental type were selected from the total queries handled during the study period. Sample of queries were evaluated according pre-determined, explicit and objective criteria using separate scales for judgmental and non-judgmental responses with a rating from 1 to 5. All relevant documentation pertaining to the query was considered for evaluation. The enquirer's perspective was evaluated by a feed back questionnaire (Fig.2). The questionnaire comprised of questions that reflected the awareness, utilization and quality of drug information services. Finally, suggestions from clinicians on DIC were also solicited. These questionnaires were distributed to physicians, postgraduate interns and other health care professionals who are utilizing the services of Drug Information Center. Towards the end of this study, filled questionnaires were collected back.

#### **RESULTS**

The study was a prospective observational study. During the study period, a total of 322 queries were handled by the drug information center. Out of these queries, 25 judgmental and 25 non-judgmental queries were randomly selected for evaluation using quality assurance form. When Non-judgmental queries were evaluated, 52% of the queries were rated as 5 which were the highest rating and 48% of the queries were rated as 4. None of the queries received rating less than 4. When judgmental queries were rated, 92% of queries were rated as 5 and only 8% of queries rated as 4. The results showed better rating for judgmental queries than non-judgmental queries. A total of 100 questionnaires were distributed and 75 completed questionnaires were collected back from clinicians. For a question on the awareness about the drug information center, 74% of them responded positively. Regarding the usage of drug information center, 54% of respondents opined positively. For a question regarding the frequency of usage, 91% of users opined that they used drug information center at least few times. When they were asked about the appropriateness of the information provided by drug information center, 95% of clinicians opined as appropriate. For a question on non receipt of answers for their queries, 15% responded that they did not receive an answer. For a question. On use of other resources, around 60% replied that they used other resources for references. For a question on the quality of the drug information center, around 60% rated it as very good, 30% rated as satisfactory, 4% rated it as excellent and 6% rated it as poor. Around 70% of clinicians rated communication skills of clinical pharmacist as excellent. 98% of the respondents have opined that there is a need for drug information center at the hospital. 37% of respondents felt that the performance of the DIC can be improved further. Some of the suggestions given by respondents were 24 hour drug information service and need for awareness program in hospital.

#### **DISCUSSION**

When a sample of documented queries were randomly selected in the category of judgmental and Non judgmental types, most of the queries were above the minimum required rating score for adequacy of documentation and questionnaire handling. One problem observed especially in case of non-judgmental queries was use of single reference to answer a query rather than multiple sources. This might be because of ready availability of Micromedex (Computerized Drug

**Fig.1.a. Quality Assurance forms**  
**EVALUATION OF ASSURANCE FOR ENQUIRY ANSWERING**  
**(Judgmental-Type)**

Query #: \_\_\_\_\_ Date: \_\_\_\_\_ Assessor: \_\_\_\_\_

**DEMOGRAPHIC DATA :**

Was the following information received noted?

*100% of answer should be yes*

Yes No

- Full name
  - Location
  - Profession
  - Relation to you
  - Time received
  - Time needed
  - Address (if necessary)
  - Age (if necessary)
  - Name the person who received the call
  - Category of requests
- 

**BACK GROUND INFORMATION**

Was the following background information needed?

*100% of answer should be yes*

Yes No

*Patient specific information:*

- Adult/child/infant/elderly
  - Medication history
  - Dosages
  - Current disease state
  - History of complications
  - Time frame for reply
  - Reason for question
  - Context of question
  - Confirm with enquirer that the question has been understood
- 

**SEARCH STRATEGY**

Were the following procedure carried out in search strategy?

*100% of answer should be yes*

Yes No

- All relevant references were be used
  - Review at least two appropriate tertiary source
  - Review at least two appropriate secondary source if necessary
  - Retrieved the primary literature if necessary
  - Consulted expert advisory, if necessary
-

**LITERATURE EVALUATION**

Was the literature evaluated in the following manner?

*100% of answer should be yes*

|  | Yes | No |
|--|-----|----|
| Various data sources (if simple were used)   |     |    |
| Response synthesized and evaluate (the data not merely summarized)                   |     |    |
| Logical and coherent conclusion were reached   |     |    |
| References were in full detail, i.e. Title, year, edition, etc., volume, page number |     |    |
| Indication made as to what is basis for choice                                       |     |    |
| Reason stated where literature considered inadequate                                 |     |    |
| Animal and/or in vitro identified as such  |     |    |
| Older information identified and reason given for its inclusion in the evaluation    |     |    |
| Personal knowledge can be substantiated by the literature                            |     |    |

**RESPONSE**

Was the following criteria met when response was given?

*100% of answer should be yes*

|   | Yes | No |
|---|-----|----|
| <i>For all responses:</i>                                       |     |    |
| Time frame used for reply                                       |     |    |
| All reference supported by the ad reference                     |     |    |
| Quinon identified as such                                       |     |    |
| Latest information used   |     |    |
| Question asked has been answered                                |     |    |
| Recommendation made are appropriate                             |     |    |
| Irrelevant information has not given                            |     |    |
| Level of reply is appropriate for the enquirer                  |     |    |
| Information is given is logically and unambiguously             |     |    |
| Complex information adequately explained                        |     |    |
| Conclusion is given   |     |    |
| <i>Written responses:</i>                                       | Yes | No |
| Legible   |     |    |
| Full references given   |     |    |
| Date of reply is given  |     |    |
| Name and status of the person preparing the reply               |     |    |
| Reply has been checked by the authorized person where necessary |     |    |
| For all responses (for internal analysis only):                 |     |    |
| Articulate  |     |    |
| Courteous   |     |    |
| Professional  |     |    |
| Concise   |     |    |
| Organized   |     |    |
| Consistent with written response (if necessary)                 |     |    |

**Fig.1.b. Quality Assurance forms  
EVALUATION OF ASSURANCE FOR ENQUIRY ANSWERING  
(Non-Judgmental Type)**

Query #:      Date:      Assessor:

**DEMOGRAPHIC DATA**

Was the following information received noted?

*100% of answer should be yes*

|  | Yes | No |
|--|-----|----|
| Full name                                |     |    |
| Location                                 |     |    |
| Profession                               |     |    |
| Date received                            |     |    |
| Time received                            |     |    |
| Time needed                              |     |    |
| Name of the person who received the call |     |    |
| Category of request                      |     |    |

**BACK GROUND INFORMATION**

Was the following background information needed?

*100% of answer should be yes*

|   | Yes | No |
|---|-----|----|
| Time frame for reply  |     |    |
| Reason for question   |     |    |
| Context of question   |     |    |
| Caution with enquirer that the question has been understood |     |    |

**SEARCH STRATEGY**

Were the following procedure carried out in search strategy?

*100% of answer should be yes*

|  | Yes | No |
|--|-----|----|
| All relevant references were be used               |     |    |
| Review of at least two appropriate tertiary source |     |    |

**LITERATURE EVALUATION**

Was the literature evaluated in the following manner?

*100% of answer should be yes*

|  | Yes | No |
|--|-----|----|
| Various data sources; not a single were used   |     |    |
| Logical and coherent conclusion were reached   |     |    |
| References were in full detail, i.e. title, year, edition, date, volume, transnumber |     |    |
| Indication used where abstracts were used  |     |    |
| Reason stated where literature considered inadequate                                 |     |    |
| Animal and/or in vitro identified as such  |     |    |
| Other information identified and reason given for its inclusion in the evaluation    |     |    |
| Personal knowledge can be substantiated by the literature                            |     |    |

**RESPONSE**

Was the following criteria met when response was given?

*100% of answer should be yes*

|   | Yes | No |
|---|-----|----|
| <i>For all responses:</i>                                       |     |    |
| Time frame met for reply  |     |    |
| All reference supported   |     |    |
| Condition identified as such                                    |     |    |
| Latest information used   |     |    |
| Question asked has been answered                                |     |    |
| Recommendation made are appropriate                             |     |    |
| Irrelevant information has not given                            |     |    |
| Level of reply is appropriate for the enquirer                  |     |    |
| Information is given as locally and internationally             |     |    |
| Complex information adequately explained                        |     |    |
| Conclusion is given   |     |    |
| <i>Written responses:</i>                                       | Yes | No |
| Legible   |     |    |
| Full references given   |     |    |
| Date of reply is given  |     |    |
| Name and status of the person preparing the reply               |     |    |
| Reply has been checked by the authorized person where necessary |     |    |
| Verbal responses: (for internal analysis only)                  |     |    |
| Articulate  |     |    |
| Courteous   |     |    |
| Professional  |     |    |
| Confident   |     |    |
| Organized   |     |    |
| Consistent with written response (if necessary)                 |     |    |

**OVERALL RATING: A minimum range of 3 should be obtained for either response**

1. Significant deficiencies made the consultation unacceptable for use. The response was incorrect, inadequate, biased, poorly documented.
2. Significant deficiencies with regard to documentation comprehensiveness, timeliness writing or other important aspect of the consultation existed, but the response was basically adequate.
3. This is the minimum acceptable level for judgmental analysis. The consultation was good but minor problem with documentation comprehensiveness, timeliness, writing or other important aspect existed.
4. Other than a minor problem with documentation, comprehensiveness, timeliness, writing or other important aspect, the response was very good.
5. The response was excellent, comprehensive and well documented and timely. For some question, an integration of data obtained from several references may be necessary to formulate a response.

**Fig.2. Feed Back Questionnaire**

|  |                  |
|--|------------------|
| 1. Are you aware of the drug information center (DIC) functioning in our hospital? |                  |
| YES   •  | NO   •           |
| 2. Have you ever utilized the services of the DIC in our Hospital?                 |                  |
| YES   •  | NO   •           |
| (If yes, how often?)   |                  |
| Regularly   •  | Sometimes   •    |
| 3. Have you received appropriate answers for your queries?                         |                  |
| YES   •  | NO   •           |
| If no, give reasons  |                  |
| Outdated   •   | Not relevant   • |
| Insufficient information   •   | Too detailed   • |
| Others   •   |                  |
| 4. Have you received the appropriate answer within an acceptable time?             |                  |
| YES   •  | NO   •           |
| 5. Is there any query for which you have not received an answer?                   |                  |
| YES   •  | NO   •           |
| If yes, specify the number _____   |                  |
| 6. Did you obtain the appropriate answer from any other sources?                   |                  |
| YES   •  | NO   •           |
| If yes, where was it obtained? (Please specify):                                   |                  |
| 7. How do you rate the performance of the DIC existing in our hospital?            |                  |
| Excellent   •  | Very good   •    |
| Satisfactory   •   | Poor   •         |
| 8. How do you rate the communication skills of the clinical pharmacist?            |                  |
| Excellent   •  | Very good   •    |
| Satisfactory   •   | Poor   •         |
| 9. Is it necessary to have a DIC in our hospital?                                  |                  |
| YES   •  | NO   •           |
| 10. Do you think the DIC can improve its performance? Please give suggestions.     |                  |
| YES   •  | NO   •           |
| If yes, please give suggestions:   |                  |

Information database) and ease of getting answers from it and in most of the cases, Micromedex alone is used as reference source. In the survey conducted among Clinicians, around 74% of clinicians were aware of the drug information service and 54% have actually utilized the services. This shows that there is a need to familiarize the drug information centre among the clinicians who did not know about its existence and need to encourage clinicians who have not utilized the services to use the services for better patient care. For a question on the appropriateness of the answer provided by the drug information center, 95% have told that the answers were

appropriate. Regarding the question on rating of communication skills of clinical pharmacist and performance of drug information center, majority of the responders have rated both as very good. This shows the functional capability of Drug information center as well as the clinical pharmacists working there. But, some physicians have rated the performance of DIC as poor and some have rated it as satisfactory. This aspect has to be looked into and care has to taken to find out lacuna and rectify it. This study showed that the results were comparable to a study reported by Beena G et al from the same center in the past<sup>7</sup>. This shows that the center is

Consistently maintaining the quality of service. This study shows that usefulness of evaluation of drug information service from the providers and enquirers perspective acts as non biased valuable tool in quality assurance of the services.

#### **CONCLUSION**

The evaluation of the quality of the drug information center based on providers and enquirers perspective showed that the service provided by the drug information center of the study hospital was of good quality. This method of dual perspective can be considered in quality assurance of patient oriented services provided by clinical pharmacists in hospital settings.

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## Role of Telecommunication in Improving Adherence of Hypertensive Patients

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### Abstract

To increase the knowledge of hypertension amongst support staff of Rhodes University, and to improve adherence of hypertensive patients using telecommunication methods. Questionnaire regarding hypertension, adherence and lifestyle was used to collect pre intervention data of 24 hypertensive patients. Medication diaries were administered and an interactive educational intervention was designed to cater to the specific needs of the target group. Simultaneously, the Short Message Service (SMS) intervention was implemented, where each patient received an SMS five minutes prior to the time required to take their medication. A reminder sheet was handed out to patients to remind them what was required in terms of lifestyle changes. At the end of two weeks, medication diaries were collected and questionnaire was used to collect post intervention data. Weight and blood pressure were measured for each patient before and after the educational intervention. It was observed that the awareness and adherence levels of hypertensive patients were low prior to the intervention. The pre-intervention analysis provided an overall measure in the three major fields, knowledge on hypertension, lifestyle and adherence, which then served as guidelines to design the educational intervention. The intervention emphasized lifestyle habits, awareness of hypertension, and underlined importance of adherence. Subsequent to the education and SMS intervention, there was a major difference in the awareness and adherence levels. Patient education and telecommunication methods increased the knowledge and adherence levels of our target group

### INTRODUCTION

It has been estimated that there would be approximately 56 million deaths globally, of which 60% would be due to non-communicable diseases.<sup>1</sup> The burden of non-communicable diseases (NCDs) results from cumulative risks and the complex risk factors resulting in NCDs are well known.<sup>2,3</sup> Hypertension is a common health condition worldwide and continues to be a risk factor for heart attacks, strokes, renal disease and blindness. Hypertension remains under diagnosed due to its "silent killer" status, causing premature death. Of the 56 million estimated deaths, it was estimated that 16 million of the deaths would be due to cardiovascular disease, especially coronary heart disease and stroke.<sup>4</sup> Stroke has a direct relation to uncontrolled blood pressure and kills more people than communicable diseases such as AIDS.<sup>5,6</sup> By the year 2025, 1 in 3 adults aged over 20 years, that is approximately 1.56 billion people worldwide are expected to have hypertension. It continues to affect low

And middle income countries more than developed countries, contrary to the popular belief that it is a 'rich man's disease'.<sup>7</sup> It is estimated that 1 in 4 South Africans between the ages of 15 and 64 years, suffer from hypertension and it continues to remain one of the leading causes of heart attacks, strokes, kidney failure and premature death.<sup>8</sup> It is also prevalent in the Eastern Cape of South Africa (where Rhodes University is situated) where, 15% urban adults and 12% rural adults are hypertensive. Out of 13.5% adults diagnosed, only 19.6% were found to be taking medication, and only 11% of these adults were adherent.<sup>9</sup> This provides evidence to the fact that hypertension remains under diagnosed, and even if diagnosed and treated, majority of the patients remain non-adherent. Care giving, decision making, communicating, managing, teaching and lifelong learning are all identified as key roles of pharmacists.<sup>10</sup> Pharmacists are in a key position to apply population specific data, quality improvement strategies, informatics, and research processes, to promote the availability of effective health care and disease prevention services. Pharmacists are required to provide

Their services in response to a dynamic and evolving set of primary local health care needs.<sup>11</sup> Health promotion is a process which involves the use of strategies that seek to foster conditions that enable populations to be healthy and to make healthy choices.<sup>12</sup> Health promotion is also an integral part of pharmaceutical care.<sup>13</sup> The change in roles of pharmacists from a product to patient-focus requires that more attention is placed on advising patients rather than merely dispensing medicines. However, factors such as lack of time, space, finance, training and perceived conflict between the professional and commercial role of pharmacists, hinder the pharmacists' involvement in health promotion.<sup>14</sup> In urban South Africa, the prevalence of hypertension is 33%,<sup>15</sup> hence, it is important to introduce educational interventions to address this problem. This study was specifically designed for low-literate, low-income category hypertensive support staff of Rhodes University to introduce interactive educational interventions.

## **MATERIAL AND METHODS**

### **Sample Group**

The study was approved by the institutional ethics committee. Hypertensive support staffs at Rhodes University were recruited with the help of the Rhodes University Sanatorium nurses. Inclusion criteria required that the study group included participants only with hypertension and were required to have a mobile phone. Though 47 possible participants were identified, due to the requirement of possessing a mobile phone, only 24 could be included in the study.

Each patient was spoken to individually and explained the nature of this study. A consent form was signed by each participant before commencement of the study.

### **Pilot study**

Questionnaire was pilot tested with five participants who were excluded from the actual study due to their co-morbid conditions of hypertension with diabetes. The questionnaire was checked for comprehension by participants and necessary changes were made.

### **Study**

The study group was finalised and each participant was interviewed in order to fill out the questionnaire. Each participant was given a medication diary, which is a self-reported measure to monitor adherence to medication. The questionnaires were analysed to understand the extent to which participants understood the condition (hypertension), adherence and lifestyle changes required by hypertensive patients. Blood pressure and weight was measured for each patient and recorded. Two weeks later, all participants were regrouped, and an interactive

educational intervention, designed specifically for our target group (low literate) was carried out. Non formal adult education strategies were used in initiating discussion and using simple (medical jargon not used) language. The emphasis was placed on the areas where participants' knowledge was lacking. Short Message Services (SMSs) were sent to the patients in the preferred language. The SMSs were sent with the aid of SIMPILL<sup>®</sup>, a private company based in Cape Town, South Africa. They allowed us to form an online dispensary, which allowed for us to key in patient's mobile numbers, dosage times and all other necessary information. The SMSs were then sent out for a period of two weeks. The old medication diaries were taken back and were assessed. A new medication diary was handed out to all the patients. An accepted cut-off point for defining proper medical adherence was set as "at least 80%" of all medicines taken in the duration of the study, implying that on a hypothetical 10 day course, medication for at least 8 days is taken without failure.<sup>16</sup> Our study, however, simplified the level of medical adherence as "not less than 83% of patients in the group taking their medication without failure in a day". This means that, in a population of 25, not less than 20 patients should take their medication for them to be considered adherent. Additionally, a fact sheet with all the key changes in lifestyle required to be made to manage hypertension was prepared and handed out to all the participants. After the SMS and the educational intervention, the hypertension questionnaire was used to record post intervention change in knowledge. Blood pressures were re-measured, medication diaries were collected and all the pre and post intervention results were assessed.

## **RESULTS**

The assessment of the hypertension questionnaire was performed to analyze the three major fields, namely, knowledge of the patients about hypertension, lifestyle of the patients, and adherence to anti-hypertensive medication. There was an overall positive impact on knowledge, lifestyle and adherence. An overall increase of 36% in the awareness of hypertension was observed after the post intervention, based on an average of 22 positive post-intervention responses compared to an average of 12 positive pre-intervention responses. The educational intervention proved to be effective, outlining particularly the awareness in patients of the correct blood pressure. A remarkable increase of 13 correct answers (54%) was observed post-intervention in this field. During pre-intervention, only 17 participants were able

To define hypertension in an acceptable manner but in the post intervention, 22 correct answers were obtained. During pre-intervention, only 12 participants felt that pharmacist were in a position to ensure adherence and to monitor patients' progress, whereas 22 felt this (an increase of 50% to 92%) after the intervention. Most patients understood that uncontrolled high blood pressure leads to a stroke but the intervention improved this knowledge by 17%.

The lifestyle-hypertension relationship was examined in a fairly concise manner with questions varying from drinking/smoking habits, to physical fitness via cooking/eating habits as well as traditional features. A very positive response was observed concerning the addition of salt in the diet. The educational intervention put a lot of emphasis on restricting addition of excess salt to food, explaining to the patients why salt is bad for their health and how it affects their health. It is to be noted that during the post-intervention, many patients admitted to have drastically reduced their salt consumption. The evidence is clear in the increase from 8 to 23 positive responses (33% to 96%). The patients were also encouraged to keep fit through regular exercise or walking to work. The patients were open to this idea as can be seen by 8% increase in willingness to exercise. Fried foods were strictly discouraged during the educational intervention and grilling as well as steaming and boiling was promoted as healthy cooking habits. A favourable increase of 21% was noted after the intervention.

Knowledge regarding adherence to medication was assessed. After the intervention, all participants acknowledged that they were able to remember to take their medications. The correct responses for taking the next dose when one dose was missed increased from 14 to 17 after the intervention. An increase from 5 to 20 participants (63%) was observed after intervention as a response to "I continue my medication even if I am well". It can be directly inferred that the SMS reminders and educational intervention resulted in improved adherence as can be observed from Table 1. The medication diary included a space for participants to write the reason, if any, why they failed to take their medicines if it happens so. On day 10, the only patient who did not take her medication admitted to having forgotten her cell phone at home, so, she only saw the SMS when she got back from work in the evening. She also indicated that she did not take the medicines as it was within four hours of her next dose, as directed in the

intervention.

As expected in a short term study, there was no significant decrease of both systolic and diastolic pressure after the intervention. An average of 2 mmHg decrease was noted in only three participants.

#### **DISCUSSION**

The use of technology in the medical field appears to be promising in the management and improvement of adherence in chronic therapy. Developing countries have to initiate innovative strategies to handle complex issues in their health care systems. Increase in non-communicable diseases, lack of funds in public sector, low literate and low income patients, weak health care infra structures, lack of access to sufficient health care providers, to mention a few.

A study reports that the use of SMS, as a reminder to a clinical appointment greatly reduced failure to attend by 27% in a gastroenterology clinic.<sup>17</sup> This lines up with the choice of sending a friendly SMS to remind patients of their medication daily. Although the duration of our study was short, adherence as well as, knowledge of self managing hypertension increased significantly. The medication diary, a self reported way of keeping a check on adherence, was effective along with SMS and education intervention. This indicates the benefits of modern technology at the service of people in improving their health and making their lives easy with a daily reminder to take their medicines.

Another study<sup>18</sup> reports that the only limitation in using SMS to remind patients is when patients do not own a mobile phone. This aspect is applicable to our study because we were restricted to recruit only 24 participants as others did not own a mobile phone. When designing studies for low income and low literate category, access of mobile phone restricts use of telecommunication. One way of promoting patient understanding of the condition as well as adherence is by improving the patient-health care provider relationship so as to eliminate any doubts concerning the condition and treatment.<sup>19</sup> In our study, it was apparent that the more time we spent with the participants the more they accepted, trusted and hence shared information freely with us. Also, the personal attention provided to participants during interviews and educational intervention was an impetus in motivating them to understand and manage their condition better. It is important to consider the situation in developing countries where there are shortages in the number of doctors, resulting in limited time allocated for patient education. It is imperative that pharmacists emphasise the role of patient education and pharmaceutical care in

South Africa and other developing countries can be used to implement telecommunication to improve patient care. Innovative ways like SMS improves interaction between health care providers and patients resulting in increased convenience and care for patients.<sup>20,21</sup> One of the major limitations of this preliminary study is non-availability of bigger sample size to carry out educational interventions. In a small sample size of low-literate, low-income hypertensive support staff in the university, the final number of participants was restricted severely by lack of participant's access to mobile phones. Another limitation is the duration of the study. As a third year undergraduate research project designed for achieving overall development of leadership qualities, team work, developing problem-solving skills and

understanding basic aspects of research, time available for undertaking research is limited. Long term follow-up of participants with more reinforcement of educational intervention is required to achieve reduction in blood pressure as well as weight loss. Future studies in following up hypertensive support staff will be aimed at long term follow-up.

**CONCLUSION**

The knowledge regarding hypertension, life style changes required to be made by hypertensive patients and adherence required to control the condition was addressed in this study. Telecommunication and patient education proved effective in achieving this aim.

**Table 1: Self reported adherence of participants in medication diary**

|        | PRE-INTERVENTION | % ADHERENCE | POST-INTERVENTION | % ADHERENCE |
|--------|------------------|-------------|-------------------|-------------|
| Day 1  | 19               | 79%         | 24                | 100%        |
| Day 2  | 21               | 87%         | 24                | 100%        |
| Day 3  | 21               | 87%         | 24                | 100%        |
| Day 4  | 16               | 65%         | 24                | 100%        |
| Day 5  | 19               | 79%         | 24                | 100%        |
| Day 6  | 20               | 83%         | 24                | 100%        |
| Day 7  | 23               | 96%         | 24                | 100%        |
| Day 8  | 16               | 65%         | 21                | 100%        |
| Day 9  | 17               | 71%         | 21                | 100%        |
| Day 10 | 19               | 79%         | 23                | 96%         |
| Day 11 | 21               | 87%         | 24                | 100%        |
| Day 12 | 15               | 63%         | 24                | 100%        |
| Day 13 | 18               | 75%         | 24                | 100%        |
| Day 14 | 19               | 79%         | 24                | 100%        |

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## A Retrospective Review of Cases of SJS and TEN in a Tertiary Care Hospital, Bangalore.

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### Background

Stevens-Johnson syndrome (SJS) and Toxic epidermal necrolysis (TEN) are rare bullous dermatologic reactions accounting for 0.05 to 2 persons per 1 million population per year. Medicinal agents are an important cause of SJS and TEN. The medical and economic impact of these reactions is therefore greater than might be expected on the basis of incidence. Therefore, we conducted a retrospective review of cases of SJS and TEN from the year 2001 to 2006 as referred by the Department of Dermatology, Victoria Hospital, Bangalore, to quantify the association of specific medicines with the same. Data were collected from the database of the department which was prepared by our faculty using the case sheets and by talking to the patients/relatives as and when cases were reported. A total of 53 cases of SJS and TEN were identified out of which 28(53%) cases were reported to have SJS and 25(47%) cases were TEN. It was found that 35(66%) were male and 18(34%) were female. Out of 53 cases 33(62%) were adults and 8(15%) were geriatric. Antibiotics were the main medicines that caused SJS followed by anticonvulsants and in case of TEN, anticonvulsants were the main agents. Out of 28 SJS cases, 17(61%) cases led to hospitalization and among 25 TEN cases, 5(20%) cases led to hospitalization. One TEN case resulted in the death of the patient, accounting for (4%) of the total number of TEN reactions. Thus, it can be concluded that ADR monitoring program helps in detecting the ADRs like SJS, TEN and many others which can help physicians in correct medical decision making and also can prove in promoting better patient care.

**Key Words:** Stevens Johnson Syndrome SJS, Toxic Epidermal Necrolysis TEN

### INTRODUCTION

An ADR has been defined by the World Health Organization as "a response to a drug which is noxious and unintended, and which occurs at the doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function"<sup>1</sup>. Among all the ADRs induced by the medication, reactions like Stevens Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) are more serious and life threatening. The incidence of toxic epidermal necrolysis is estimated at 0.4 to 1.2 cases per million person-years<sup>2,3,4,5</sup> and of Stevens-Johnson syndrome at 1 to 6 cases per million person-years.<sup>2,3</sup> Although infrequent, these conditions may kill or severely disable previously healthy people. A few cases have prompted the withdrawal of newly released

medicines. Stevens-Johnson syndrome (SJS) may also present as a dermatologic emergency characterized by purpuric macules and targetoid lesions; full-thickness epidermal necrosis, although with lesser detachment of the cutaneous surface and mucous membrane involvement and severe constitutional symptoms.<sup>6</sup> Medicines are an important cause of Stevens-Johnson syndrome, but infections or a combination of infections and medicines has also been implicated.<sup>7</sup> TEN is an acute dermatologic disease the presentation of which may constitute a true emergency. The disorder is characterized by widespread erythematous macules and targetoid lesions; full-thickness epidermal necrosis, at least focally; and involvement of more than 30% of the cutaneous surface. Commonly, the mucous membranes are also involved. Nearly all cases of TEN are induced by medications, and the mortality rate can approach 40%. The medical and economic impact of these disorders is therefore greater than might be expected on the basis of

incidence. Better information on these reactions should help in better medical decision making.<sup>6</sup> Therefore, we conducted a retrospective review of cases admitted to Victoria Hospital, Bangalore with SJS and TEN from 2001 December to quantify the association of specific medicines with the same.

**METHODOLOGY**

The data of both in-patients and out-patients as referred to the Department of Pharmacy Practice by the Department of Dermatology, Victoria Hospital, Bangalore, during 2001 to 2006 were included in the study. The retrospective data were collected from the database of the department which was prepared by the department faculty using the case sheets and by talking to the patients/relatives as and when cases were reported. Demographic details, causative medicines implicated and the management out-come were noted from the database.

**RESULTS AND DISCUSSION**

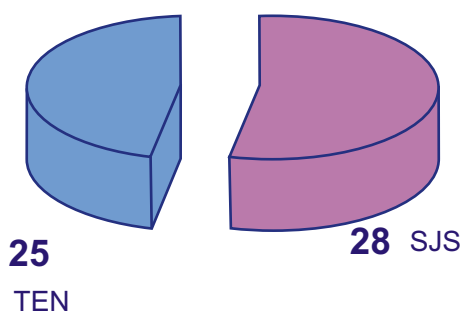
A total of 53 cases of SJS and TEN were identified from the database. From the demographic details of the patients, it was found that 28(53%) cases were reported to have SJS and 25(47%) cases had TEN (Figure 1). Among 53 cases, 35 (66%) were male and 18(34%) were female (Figure 2). It was seen that 33(62%) were adults and 8(15%) were geriatrics (Figure 3). Skin was the main

part affected 49(92%) in majority of the cases. The therapeutic class of the medicines that caused the reactions were analyzed and found that highest incidence of reactions was noted with antibiotics 19(36%) in case of SJS. Antibiotics were implicated in 4(1%) cases of TEN. Anticonvulsants were the causative drugs in 6(1%) cases of SJS and 7(1%) cases of TEN. Ciprofloxacin was the most common antibiotic which caused SJS (5 cases, 26%) and Ofloxacin (3 cases, 14%) attributed to maximum cases of TEN followed by Anticonvulsant-Phenytoin caused 5(83%) of SJS and 5(71%) of TEN (Figure 4, Figure 5). In many cases it was not possible to identify the exact cause for the reaction which was due to either lack of knowledge in patients or patient could not remember which medicine he/she consumed. Out of 28 SJS cases, it was found that 17(61%) cases led to hospitalization and 5(18%) cases led to prolonged hospitalization. Among 25 TEN cases, 5(20%) cases led to hospitalization and 10(40%) cases led to prolonged hospitalization. One TEN case resulted in the death of the patient accounting for (4%) of the total number of TEN reactions.

**CONCLUSION**

From our study we found that the use of antibiotics and anticonvulsants is associated with the risk of SJS or TEN. Hence, a registry for these medicines is required which

**Figure 1: Total number of SJS and TEN**



**Figure 2: Demographic details of patients experiencing SJS and TEN**

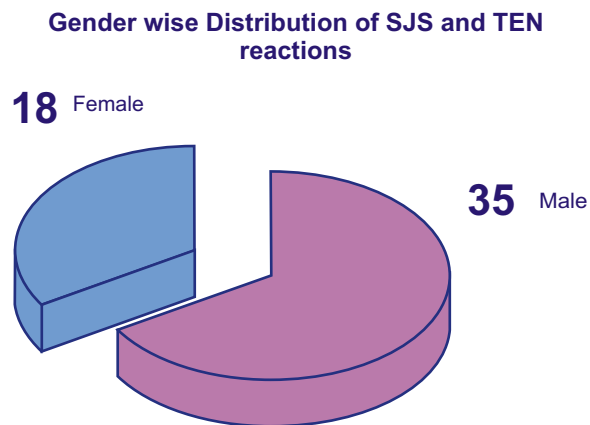


Figure 3: Depicts SJS and TEN categorized based on age of the patients

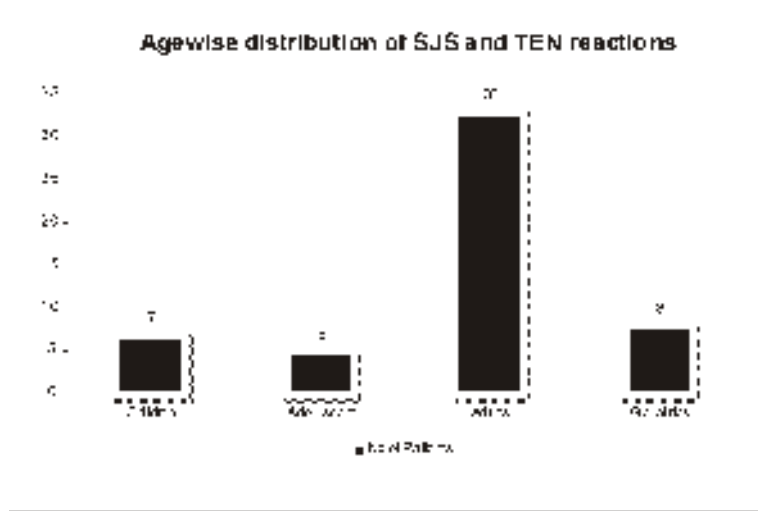


Figure 4: Shows the medicines that cause SJS AND TEN

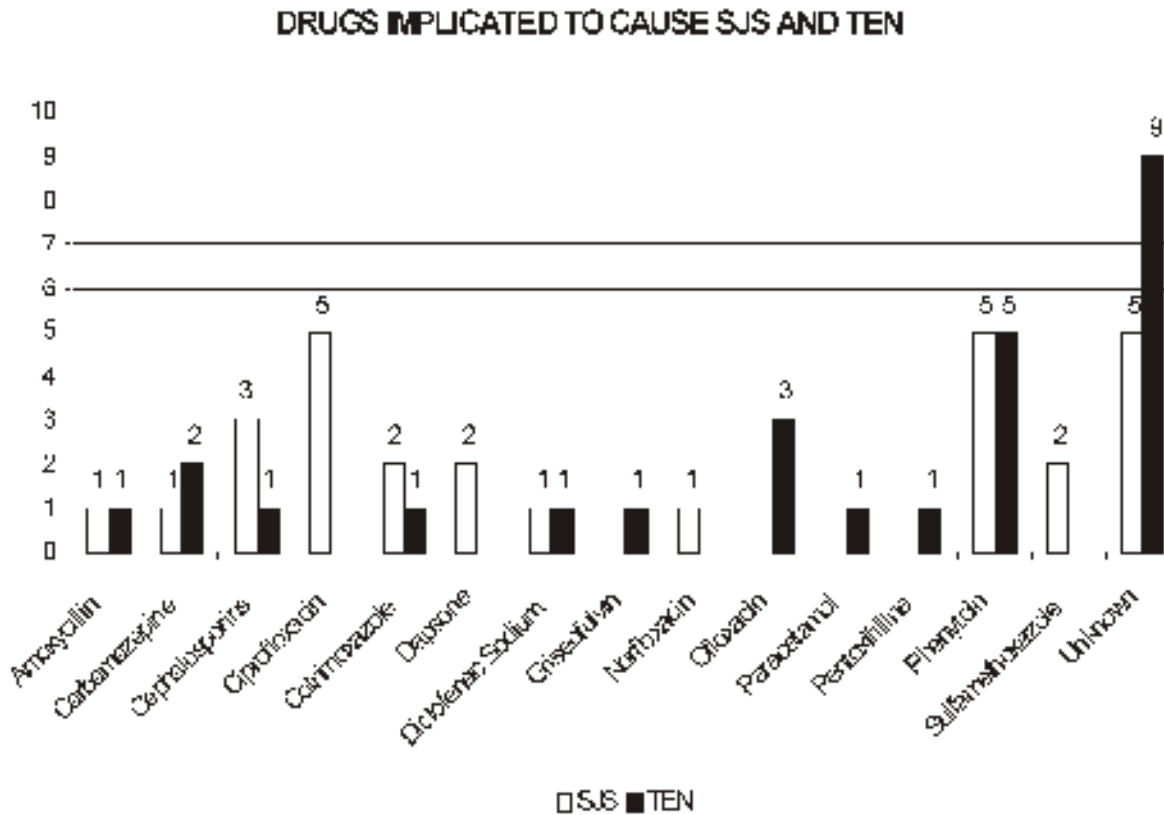


Figure 5: shows the Therapeutic Class of medicines that cause SJS AND TEN

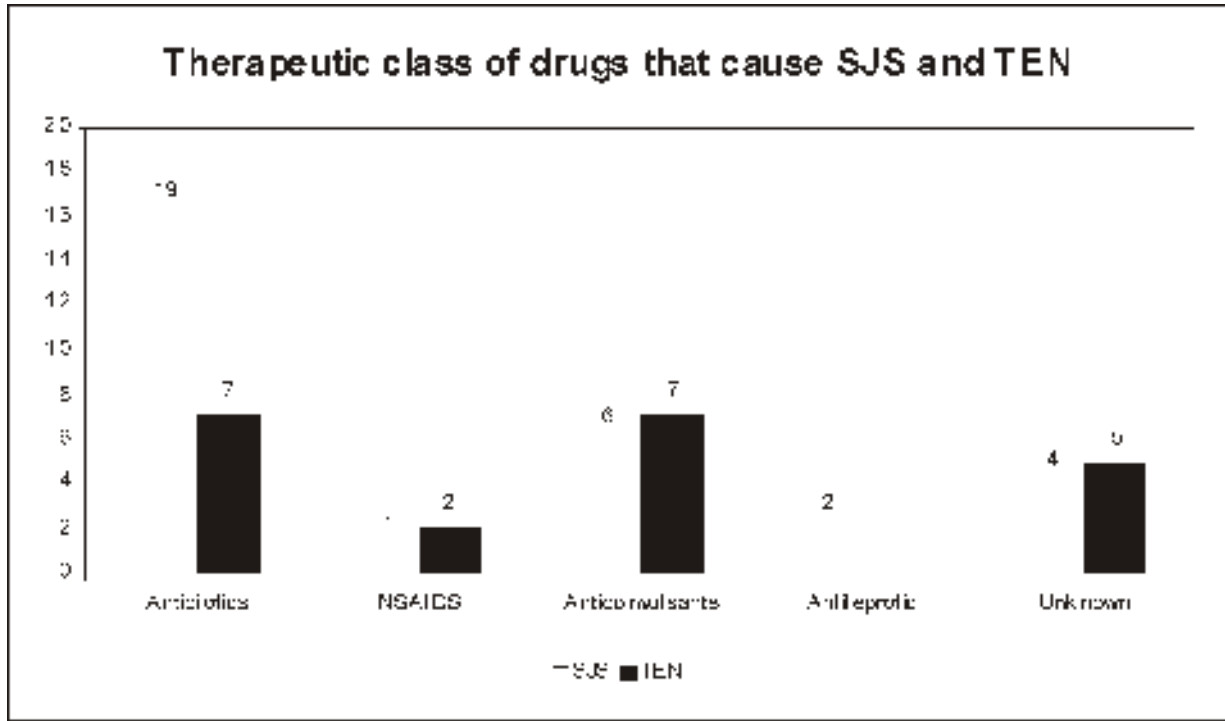
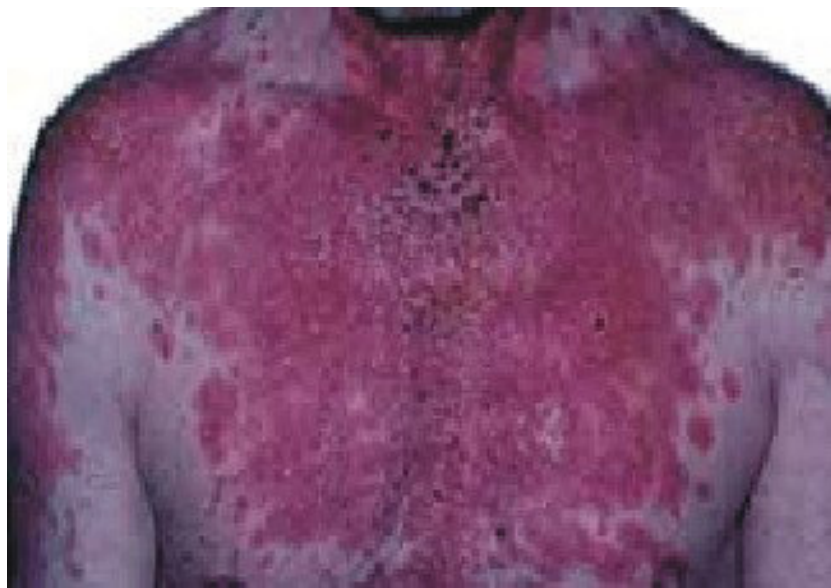


Figure 6: Representative picture of SJS.



**Figure 7: Representative picture of TEN.**



Will help in determining the national incidence of SJS and TEN. This will further enhance our knowledge of these reactions. Thus, it can be concluded that ADR monitoring program helps in detecting the ADRs like SJS, TEN and many others which can help physicians in correct medical decision making and can help in promoting better patient care.

#### **ACKNOWLEDGEMENT**

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## Quinine Induced Temporary Visual Loss - A Case Report

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### Background

*Cinchona bark, which contains quinine, is known to have been used in Europe since 1633 for prophylaxis and treatment of malaria. The commonest symptoms of overdose are tinnitus, nausea, vomiting, hearing impairment, vasodilation and sweating<sup>1,2</sup>. While all of the cinchona alkaloids can cause visual disturbances, only quinine is known to cause blindness.<sup>3</sup> The commonest permanent disability is visual field restriction, which is frequently severe and may require the patient to be placed on the blind register<sup>1,2,4</sup>. The vast majority of patients show some improvement with transient blindness lasting for 1 h to 50 days. Between 8 and 14 h is the typical of the length of time between developing blindness and the first perception of light. In general, visual recovery is only partial, with the peripheral vision being the most affected.*

*Key words: Quinine, Visual loss.*

### DISCUSSION

Disturbance of vision have been reported in 17% of patients with quinine overdose<sup>5</sup>, 75% of these patients were completely blind. However, once daily dose of Quinine may cause alteration in colour vision, visual field restriction or blurring of vision. Typically, ocular symptoms develop 4-15h after overdose<sup>1, 5, 6</sup>. The exact mechanism of visual loss has been debated since the 1880's<sup>1,7</sup> and is still uncertain. It was initially felt that blindness occurred due to retinal ischemia secondary to retinal arteriolar constriction.<sup>8, 9, 10</sup> However, blindness has been observed in patients whose retinal arteriolar calibre remained normal<sup>6, 11</sup> and others with normal retinal arteriolar calibre when blindness occurred, several days or weeks later after sight had returned, developed arteriolar constriction.<sup>1,2,5,9,6,12,13,4,15</sup> This suggests that blindness is not due to retinal arteriolar constriction. Support for the hypothesis that blindness results from a direct toxic effect of quinine on the retina comes from electroretinographic (ERG) studies following quinine overdose. Measures to dilate retinal arterioles have been used in the treatment of blindness due to quinine overdose for 45 years,<sup>16, 17</sup> the commonest method used has been SGB (Stellate ganglion block). Other methods have been used to achieve retinal arteriolar vasodilation including intravenous<sup>8</sup>, inhaled<sup>1,4,9, 18,19</sup> and retrobulbar<sup>2,19,20</sup> vasodilators, carbon-dioxide inhalation<sup>4</sup> and reducing intraocular pressure by anterior chamber paracentesis<sup>4</sup>.

These methods have never been studied in a controlled trial but case reports do not show any clear evidence of benefit. This is further support for the idea that blindness following quinine overdose is not due to vasoconstriction. Ocular massage, recumbent posture<sup>1</sup> and hyperbaric oxygen<sup>22</sup> have also been reported as beneficial in single case reports. Peritoneal dialysis, haemodialysis, exchange transfusion and charcoal and resin haemoperfusion (if oral ingestion of quinine tablets) only remove a very small quantity of quinine and have not been proven to be of any therapeutic benefit<sup>23, 24,25,26,27</sup>. This is presumed to be due to quinine being strongly bound to plasma proteins and having a large volume of distribution<sup>26,27</sup>.

### The case

A 24y year old male, suffering from moderate-high grade fever intermittently since a week having tested Malaria falciparum positive was treated with oral chloroquine 15mg & Paracetamol tablets. The symptoms still persisted and hence reported to the emergency at around 6.30p.m. Upon investigation, the patient was diagnosed to have cerebral Malaria. He was then shifted to the MICU, at 8.30 p.m and treated with a loading dose of 1200mg quinine IV in 5% dextrose infusion, artesunate 120mg IV in 0.9% normal saline, along with IV omeprazole 20mg & IV ondansetron 8mg. The patient had acute attacks of psychoses for which the patient was given IV haloperidol. In the morning at around 6.45 a.m, the patient was given a second dose of 600 mg of quinine IV. Within two hours after administration of second dose

of quinine intravenously, the patient complained his inability to see objects and people attending him. Also, the patient was not responding to finger counting. The resident doctor upon thoroughly examining the patient called on the ophthalmologist. Fundoscopic examination revealed that there was no evidence of retinal ischemia with vasoconstriction or retinal pallor and the ophthalmological examination was essentially normal. Later, the physician suspected that it could be due to other causes & hence spontaneously reported as an ADR. Upon systematically analyzing the ADR report, the vision loss was suspected to have been caused by quinine. Careful literature survey was carried out to assess the causality of the reported ADR. Literature survey revealed that quinine can cause temporary to permanent visual loss at plasma concentration levels of 10-15mcg/ml. Upon confirmation of the causality, quinine was withdrawn from the treatment of the patient. Literature survey revealed that this type of ADR induced by quinine can be managed by administering hyperbaric oxygen to the patient. Although there is no known definite treatment for quinine induced blindness, early withdrawal of quinine from the treatment regimen and by supplemental oxygen administration is suggested in the literature. Supportive management was done by maintaining good fluid and electrolyte balance. This treatment was adopted by the physician attending the patient. By evening of the same day, the patient gradually could see faintly and finally, regained his vision. The patient was treated for Malaria only with Artesunate 60mg OD and ofloxacin and was discharged two days later after he was found to be stable.

#### CONCLUSION

Though commonly not encountered, quinine overdose may lead to temporary or permanent blindness at a plasma concentration of 10-15mcg/ml. Hence, it is essential to monitor the plasma concentration of quinine in patients treated for Malaria especially with IV quinine. Though the plasma concentration of quinine was not monitored in the present case, timely reporting of this ADR helped the patient to regain his sight. The present case emphasizes the importance of monitoring of the plasma concentration of potentially harmful drugs and more importantly it highlights the importance of adverse drug reaction monitoring.

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## A Case Study of Cefuroxime/Oxcarbazepine Induced Stevens - Johnson Syndrome

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### Background

Any prescribed medication for any patient can cause adverse effects which sometimes can be life threatening. So, responsibility lies on the health care professionals to be cautious while prescribing for their patients<sup>1</sup>. They must be asked for history of any drug allergies and instruct them to report immediately if any side effects occur. This is particularly important for a few categories of drugs like NSAIDs, antibiotics like penicillin's, cephalosporin's, and anticonvulsants like diphenylhydantoin and carbamazepine. These are well known to cause severe drug reactions like Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).<sup>2,3</sup> SJS and TEN is a potentially fatal condition that can manifest with severe skin and mucosal reaction. It also involves other sites of mucosal involvement like in the eyes and vaginal mucosa. There are no strict guidelines available for treating SJS or TEN. Use of steroidal agents to treat these conditions is still a controversy.<sup>4</sup> According to the epidemiological studies published, the average mortality rate for SJS was estimated to be about 1-5% and TEN to be about 25-35%.<sup>5,6,7</sup> Superimposed infections and severe mucosal involvement are more often associated with higher mortality. Therefore, isolating the patient to an aseptic area could be the primary step for managing these conditions along with good nursing, which can reduce the open skin lesion infection and can contribute to a fast recovery.

### CASE REPORT

A 33 yr old female patient was presented to the emergency department with complaints of worsening maculopapular rashes all over the body (face, chest, abdomen, back and limbs). Lesions were also seen on her oral cavity, throat and genital. She was complaining of severe pain in her throat and difficulty in opening her mouth. These symptoms clearly indicated SJS. Past medical history revealed that she is a known case of micro adenoma pituitary and vertiginous epilepsy, for which tablet oxcarbamazepine and tablet clobazam were prescribed since 12 days. Present history says that, the patient was suffering from upper respiratory tract infections for which she had gone to a local doctor, where she was advised to take tablet cefuroxime, tablet paracetamol, and tablet diclofenac sodium. On examination, she was found to be conscious and oriented, her vital signs were normal. Conjunctival congestion was present. Her hematological report showed mild decrease in hemoglobin and packed cell volume (PCV). Peripheral blood smear reported normocytic normochromic blood picture with relative neutrophilia. Elevated erythrocyte sedimentation rate (ESR) was also

seen. Her urine report showed presence of epithelial cells and pus cells. Microbiological report confirmed the presence of colonies of klebsiella. The presumptive cause of SJS could have been cefuroxime, paracetamol, diclofenac, oxcarbamazepine or clobazam. Past medication history revealed that patient was exposed earlier to paracetamol and diclofenac and had no signs of SJS or any other drug reactions on previous exposures. The reaction was assessed by using WHO and Naranjo scale. Literature search was also done to know the incidence of SJS caused by each drug to which the patient was exposed. The search could not support any evidence of SJS caused by tablet clobazam. Therefore, tablet clobazam was rechallenged to rule it out as a causative agent to cause SJS. After the drug was rechallenged, her SJS didn't worsen. So, tab. clobazam was reintroduced into her prescription. This suggested that the possible drug responsible was cefuroxime or oxcarbamazepine. The patient's treatment included antibiotics, corticosteroids and other symptomatic treatments. Empirical therapy was initiated with 100 mg of I.V netilmycin followed by 100 ml of I.V metronidazole on the first day. Along with these, 4mg of I.V betamethasone, 40 mg of pantoprazole, 4 mg of I.V Ondansetron and 50 mg I.V tramadol were given for her

other symptomatic complaints. IV fluids were also supplemented as patient was unable to take orally and was advised to be nil per oral. The infection caused by the skin lesions were treated with metronidazole gel twice daily and triamcinolone oral paste was advised for replacement therapy in adrenal insufficiency for her last medical condition. Mixture of hydroxypropyl methylcellulose (0.7%) and saline (0.45%) was used as an ocular lubricant. Ciprofloxacin eye drops and 180 mg oral fexofenadine were additionally included on the second day, while tramadol and I.V fluids were stopped. On the remaining days, topical fluticasone cream, 10 mg of tab. clobazam, bisacodyl suppositories were advised, milk of magnesia and paracetamol were included whenever patient complained of heartburn and pain



On the seventh day, patient's condition improved and she was able to take the medication orally. So I.V pantoprazole was changed to tab pantoprazole and topical xylocaine was included to reduce the pain. The patient was closely monitored for 4 days in the medical intensive care unit (MICU), after which, when her lesions reduced in size and number and was stable, she was shifted to a private ward. She was discharged after a total of 7 days of hospital stay. She was advised to follow up with the ophthalmology and dermatology department as an outpatient for her ongoing complaint of conjunctival congestion and skin lesions in their respective departments.

#### CONCLUSION

Cephalosporins and oxcarbamazepine are well reported in literature for causing SJS. Therefore, cefuroxime and oxcarbazepine were not rechallenged to avoid further fatal reactions. This ADR was the cause for a prolonged hospitalization with considerable suffering and discomfort. Hence, patients must be educated as to

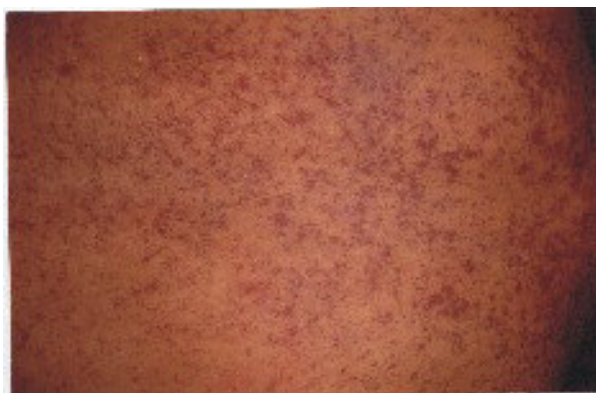
respectively can be avoided to those patients prescribed with high risk groups of drugs causing SJS and TEN which can be fatal.

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**Editor, compiler, as author**

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Kimura J, Shibasaki H, editors. *Recent advances in clinical neurophysiology*. Proceedings of the 10th International Congress of EMG and Clinical Neurophysiology; 1995 Oct 15-19; Kyoto, Japan. Amsterdam: Elsevier; 1996.

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Kaplan SJ. *Post-hospital home health care: the elderly's access and utilization [dissertation]*. St. Louis (MO): Washington Univ.; 1995.

#### Patent

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