

## Clinical Pharmacy Services Improve Effectiveness of Therapeutic Regimen

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### Abstract

Clinical pharmacy services aim at effective, safe and economic therapeutic outcomes. History of pharmacy services reveals that the term 'clinical pharmacy' is in use since 1953. However, the structured concept of "clinical pharmacy" crystallized in late 1960s. The focus was reorienting the role of pharmacist from product preparation to patient centric services. This emanated from the ever increasing number of new drug molecules and complex formulations of medicines entering the therapeutic arena. The fulfilment of the aims of safe, economic and effective therapy became more and more complex and complicated due to emergence of poly-pharmacy practice. In search of solace, rational usage of medicines occupied central stage and optimization of therapy became the ultimate goal. Clinical pharmacist involves in ensuring rational usage of drugs in individual patient. The set objectives demand that pharmacists must acquire and implement deep knowledge of biopharmaceutics, clinical pharmacokinetics, pharmacology, toxicology and therapeutics as a whole to individualize medication and perform effective therapeutic drug monitoring. Biopharmaceutic basis of therapeutics relies on pharmacokinetic parameters of the dosage form in relation to the metabolic and elimination profile of the patient. Thus Clinical Pharmacy practice is a super specialty area in which each patient is clinically different based on his medical records and laboratory data. Therefore, the patient deserves dosage regimen specially designed according to her/his own profile. Of course, assessment of the outcomes and recommendations for dose adjustment to minimize adverse drug reactions along with economic aspects of therapy form integral part of clinical pharmacy service.

**Keywords:** Clinical Pharmacy; Clinical Pharmacokinetics; Rational Therapy; Pharmaceutical Care

### Introduction

Emergence of plethora of medicinal drugs has its own ramifications on therapeutic outcomes. The reality of ever increasing adverse drug reactions from prescription medicines has been well perceived by prescribers and abundantly documented by researchers. Thus the menace of prescription drugs is no secret any more. The solace is only in clinical pharmacist's intervention and the results are encouraging because of application of expertise to maximise drug effect and minimize toxicities. In practice set up clinical pharmacists involve directly with patients and health care providers like physicians, nurses to give information and guide patients about the effects of prescription drugs, dosage and potential side effects. They also educate patients or their care givers and give

suggestions on how to adhere to an effective and safe drug therapy program for total compliance.

In UK the practice was initiated as regular ward rounds and review of medication chart to ensure safe prescribing [1]. This objective was pioneered and pursued by Graham Calder and JW Barnett. To be precise the pioneering shift in practice protocol began with 'Ward Pharmacy' and that was succeeded by clinical pharmacy [2]. Ward pharmacy came into existence in 1960s, to overcome the reported errors in administration of medicines to the patients [3,4]. In the late 1960s the concept of "clinical pharmacy" began sprouting to further reorient the practice of pharmacy as patient centric and involvement of Pharmacists in drug usage [5]. This transition

in the role of Pharmacist from product oriented to patient oriented utilized his deep knowledge and expertise in pharmaceuticals, pharmacology, toxicology, clinical pharmacokinetics, analysis, pharmacotherapeutics and pharmacoeconomics to individualize the medication to be used. It includes but is not limited to patient interviews on drug therapy, participation in patient care rounds, adverse drug reaction reporting, therapeutic drug monitoring, answering drug information queries, and patient counselling on discharge/counselling of ambulatory patients.

Assessment of the effectiveness of ward pharmacy eventually proved useful and confirmed reduction in the incidence of discrepancies between prescribed and administered drug dosage. Nurses and doctors often consulted ward pharmacists about medicines and their use, thereby increasing their advisory role [6]. Ward pharmacy's valuable services were also commended by the Department of Health in 1970 [4].

Another landmark development in 1970 was inception of drug information service. This is an area where information technology is now extensively adopted for prompt and accurately evaluated information dissemination to all health care providers. This is part and parcel of clinical pharmacy practice.

As early as in 1983, the United Kingdom Clinical Pharmacy Association (UKCPA) elaborated on role and responsibilities of clinical pharmacy services [5], which *inter alia* included:

- Education of patients on drug use - on appropriate use of medicines, to be taken during treatment and anticipated side effects;
- Education of health care staff - by regular ward visits, participating in ward rounds and unit meetings, by lectures, seminars, bulletins, formularies and meetings with prescribers (via drug and therapeutics committees);
- Advice and information on drugs - pharmacists to help solve clinical problems in individual patients;
- Pharmaceutical expertise applied to clinical problems - for example, in the design and preparation of the most suitable means of drug administration for a particular patient, in the provision of paediatric dosage forms, aseptic dispensing and intravenous additive services, in the formulation and preparation of special parenteral products and in the design of systems to improve patient compliance and reduce drug administration error;

- Surveillance of drug use - to monitor patient compliance, to contribute to the monitoring and assessment of the effectiveness of treatment and to help develop drug usage review, to detect and report adverse drug reactions, to measure and interpret plasma drug levels and to design dosage regimens”.

All the above initiatives and enterprising activities were brain child of practicing pharmacists themselves. Their collective, and co-ordinated efforts culminated in foundation of specialist association UKCPA to achieve the goal of safety, improved efficacy and economy of medication. Eventually the results got appreciation from every quarter as was evident from the Nuffield foundation report of 1986 [7]. Regional Pharmaceutical Officers' Committee statement 1988 [8].

In 1983, Nuffield foundation (UK) had appointed a committee under the Chairmanship of Sir Kenneth Clucas [7], to consider the present and future structure of the practice of pharmacy in its several branches and its potential contribution to health care and to review the education and training of pharmacists accordingly.

#### Summary of the committee's report is reproduced below

“The most significant development in hospital pharmacy and possibly the most interesting activities within the profession has been the introduction of clinical pharmacy; this has owed much to the initiative, dedication and enthusiasm of individuals, both pharmacists and doctors [8-11]. For the most part this has been done without additional resources through the expedient of automating what can be automated and delegating what can be delegated, thus releasing professional resources for professional work. Attempts to assess benefits of this work against its costs have proved difficult. We think clinical pharmacy looks so promising as to warrant its extension to all hospitals.

Another significant development has been the acceptance of the principle of specialization both between different areas of pharmacy and between different medical areas within clinical pharmacy. We consider this process both inevitable and desirable.

One desirable consequence of the development of clinical pharmacy is the increasing cooperation to which it has led between the health care professions. The principal beneficiary of this is the patient. There is a scope for increasing the pharmacist's contribution to inter-professional cooperation in such areas as ADRs reporting and clinical trials”.

As a consequence of the developments reported hereunto transition of ward pharmacy to clinical pharmacy became inevitable. This necessitated introduction of new services like drug information as explained earlier and therapeutic drug monitoring. As a result of the new roles the term clinical pharmacy emerged as true description of the practice reorientation. In UK it was endorsed by the Department of Health in 1988 as a measure to improve the cost-effective use of medicines and enhancing patient care [9-11].

In all fairness, the study of the available literature reveals that hospital pharmacists adopted this new role voluntarily and willingly in the interest of patients. The contribution of clinical pharmacists is additive to, and not a substitute for the role of the doctor by any means. Both therapeutic and economic benefits of clinical pharmacy practice are well established and appreciated across the globe.

As per World Health Organisation (WHO) working party report [12], clinical pharmacy has been defined as follows: "Clinical pharmacy services involve the pharmacist in the solution of medicine-related clinical problems, the provision of advice and information on medicines, education of in- and out-patients and also of health care staff, therapeutic drug monitoring and any other task which will promote the rational use of medicines".

The European Society of Clinical Pharmacy (ESCP) in association with the Societe Francaise de Pharmacie Clinique (SFPC) and UKCPA [12], have defined clinical pharmacy as under: "Clinical pharmacy may be defined as the attitudes, skills and knowledge required by pharmacists in order to ensure the appropriate, effective, safe and economic use of drugs by individual patients and by society".

A timeline of developments leading to evolution of clinical pharmacy has been described by the author [13]. Those events inched towards setting up of full-fledged clinical pharmacy discipline across the developed world. The pharmacists involved at every stage of timeline contributed in innovative ways towards making medication more safe, more efficacious and economic for the establishment as well as patients.

### The roles of clinical pharmacists

Clinical pharmacists are authentic source of advice on the optimal use of medicines. This involves advice at a policy making level

and at the individual patient level too. Of course the best model is multidisciplinary team activity with active engagement and involvement of various health care providers focussed on outcome of therapy. The advisory role focuses both on clinical and financial aspect. Quality of medicine and competitive price plays important role in efficacy and affordability of therapy. Pharmacists have unique knowledge and expertise in both of these areas and thus proved very helpful in containing costs and addressing the issues relating reduction of risks and health hazards associated with the use of modern medicines. Clinical Pharmacists play major role in providing drug information to health care personnel as well as public at large. Education and training of pharmacists and other health care team members and for other groups in the hospital is another area which improves perfection in practice. Clinical Pharmacists also play key roles in improving patients' abilities to use their medicines properly and faithfully comply with the instructions for use of medicines. With advances in drug discovery and development process, clinical pharmacists' role in clinical trials has become inevitable. On the other hand practice based research for advancing the profession has assumed an important place in pharmaceutical care and it provides ample opportunity for scientific publications.

Clinical pharmacy services' role and practice guidelines may be summarized on the basis of research publications and Standards prescribed in US [14,15] as under:

- Design, implementation, monitoring, evaluation, and modification of pharmacotherapy to ensure safe, effective, and economical patient care that is both affordable and accessible.
- Prospective formulation of individualized dosage regimen on the basis of the indication(s) for the medication(s), drug product selection, laboratory data, medical history including allergies and concurrent drug therapies, pharmacokinetic parameters of the drug (s), and patients' clinical conditions.
- Using interviews, physical assessment skills, and interpretation of laboratory test results, monitor therapy for its effects or adverse reactions:
  - Designing treatment plans and advising prescribers on their implementation.
  - Using established therapeutic protocols.
  - Independently prescribing or adjusting drug therapy in instances where supportive legislation or regulations exist.

- Effective patient counselling on use of prescription and non-prescription drugs, devices, injectables, and smart dosage forms; application of topical products; assessment of patients' comprehension ability to correctly use devices.

The standards and guidelines also suggest regular evaluation of literature to assess data reliability and validity and clinical application of the findings. These documents also advocate for quality assurance programmes and continuous improvement goal. Definitely excellent scientific writing skill and publication activities are indispensable for becoming clinical pharmacist of repute.

### Types of practice setup

There are two types of practice setup. The first one is institutional and the second one is in ambulatory patient care which is also known as non-institutional setting. Both the areas have been very well and thoroughly studied as evident from the volume of research publications available. The institutional part has been extensively dealt with in the introduction section of this paper.

Publications related to studies in non-institutional settings reveal that clinical pharmacy services has potentially improved disease control, taken care of avoidable adverse drug reactions and potential noncompliance issues in ambulatory patients [16,17]. The pharmacist should strive to ensure a positive therapeutic outcome with the lowest probability of an adverse reaction or lack of effect. Standards of practice for clinical pharmacists in non-institutional settings have been developed [18,19], which are useful for the practitioners by all means.

### Practice modules

Practice modules in clinical pharmacy are aimed to develop critical analysis and medication therapy management skill for the delivery of pharmaceutical care. Actually, in the developed world, the continuing professional development (CPD) programme focuses on this aspect. The key components of the module reverberate around identifying actual and potential drug therapy problems in patient. How to resolve that and how to prevent that problem determines the success of clinical pharmacy practice. Thus assessment, planning, implementation and evaluation to measure outcomes are key steps for the practice module. This general structural feature is applicable to all types of modules like Pharmaceutical care delivery, medication therapy management, patient-centred primary care, individualised medication assessment and planning. Guidelines and recommendations on standard of practice have

been devised by American College of Clinical Pharmacy [20]. This is an important treasure for the practitioners to build upon the basic foundation in this specialized area. A prototype practice module is presented in figure 1. The module is a cyclic process which continues in progression until optimisation of therapy. Optimisation of therapy is achieved when all the potential risk issues are satisfactorily addressed. In case of long term treatment of chronic diseases clinical pharmacy service proves immensely useful in stabilising the patient and improving quality of life which is basic expectation of patient.

**Figure 1:** Prototype practice module of clinical pharmacy.

### Discussion

Clinical pharmacy practice is a step forward in the direction of thwarting medication menace and assured rational use of medicines. Health and comfort of the patient is principal objective, which is attained through continuous research and infusion of innovations in the practice settings. It is a research intensive area in pharmacy practice and importance of pharmaceutical care lies in the intensity and scale of implementation of validated new research findings in the field of clinical pharmacy. Design, evaluation and monitoring of patient care plans are preliminary steps whereas; recording the outcomes and its evaluation to assess and reassess success rates is final step to validate the plan. In all the cases, the care plans are patient specific and continuous follow-up is the general rule. Thus, clinical pharmacy provides direct patient care for medication related needs. Optimization of patients medication needs is the ultimate success.

### Conclusion

The lack of clinical pharmacy service results in underserved pharmaceutical care to the masses and underutilization of pharma-

cists' knowledge and expertise. The patient is deprived of essential services in terms of therapeutic drug monitoring (TDM), adverse drug reaction monitoring, drug information, and rational use of medicines and unnecessarily posed to health hazards. The in-service training for the nursing and medical staff on special fronts of bioavailability, bioequivalence, drug interactions and dosage form related compliance issues are compromised. The ultimate result is truncated success in health care goals. Sooner the policy makers of health sector realize the importance of clinical pharmacy is better in the interests of patients.

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