

The History of Pharmacy, Present-day Pharmaceutical Care and the Future Clinical Pharmacy in South Africa.

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Abstract

Globally, the role of a Pharmacist has, in the past few decades, evolved from being product-focused; towards being patient-focused. In line with this, the South African Pharmacy Council has gazette a “Scopes of Practice and Qualifications for Specialist Pharmacists” in South Africa. The adoption of these proposals could pave way for creation of posts for clinical pharmacists at every hospital. This might, in turn motivate pharmacists to specialize in in various disciplines, including clinical pharmacy.

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Pharmacy Prior to the 1940's

During this period, pharmacy was an occupation where practitioners were trained by apprenticeship, i.e., practitioners mastered the trade on the job, rather than in school [1]. Pharmacy was considered an art that did not require theoretical knowledge, but rather skill to be learned through handling and preparing of commonly used remedies. [1] At that time, pharmacists only performed the apothecary role (compounding and dispensing). There were no laws to enforce safety of the medicines and to make sure that pharmaceutical products sold were unadulterated. The public relied on the pharmacist for safety of the pharmaceutical products yet; many of those medicines were times inefficacious, mislabeled and unsafe for consumption [1].

In 1906, the United States (US) federal government passed the Pure Food and Drug Act, which later the US Food and Drug Administration (FDA) to enforce penalties for mislabeling and adulteration. However, this piece of legislation did not do much to address the issue of efficacy and as such, manufacturers, prescribers and dispensers found many loopholes through which they could evade prosecution [1]. In 1937, 73 deaths attributed to ingestion of a toxic elixir containing Sulfanilamide triggered the US federal government to enact the Food, Drug and Cosmetic Act in 1938, which afforded the FDA greater authority to enforce standards of safety and efficacy of medicinal products. During this time, there was no formal legislation to categorise medicines into prescriptions-only and non-prescription products and as such, patients did not need to visit a physician if they needed any medicinal product [1]. Indirectly, therefore, pharmacists prescribed the medicines they dispensed. Pharmacists also provided advice to patients on usage of the medicinal products they dispensed [2].

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Just like it is currently, pharmacists were accessible and were visited frequently, which made them the first point of entry into the healthcare system [1]. In 1910, however, Abraham Flexner had been appointed to study the medical education system and in his report, he discredited pharmacy as a profession simply because pharmacists carry out orders given by physicians. [1] Based on this report, the American Association of Colleges of Pharmacy (ACCP) commissioned a study which served as a basis for the establishment of a four-year Baccalaureate Pharmaciae (Bachelor of Pharmacy) program which later served as a pre-requisite for entry into the pharmacy program [2].

Pharmacy from the 1940's to Early 1970's

This period saw significant changes regarding the organization, delivery and financing of healthcare. However, pharmacists also began to see their major role in medicine use management diminish: large wholesale manufacture of pharmaceutical products was taken over by large-scale manufacturers. [1] The increased demand for pharmaceutical services coupled with technological advancements resulted in the need for fabrication of medicines in standardized dosage forms such as tablets, capsules, syrups, solutions, elixirs, etc. [1] In 1951, in the US, the Food, Drug and Cosmetic Act was amended to create a prescription-only medicines category. The label on these medicines contained a caution against "dispensing without a prescription." [1] This resulted in creation of a new class of medicines that pharmacists were not allowed to dispense without a prescription from a licensed prescriber. At the same time, the American Pharmaceutical Association generated a Code of Ethics which prohibited pharmacists from discussing therapeutic use or composition of the medicines with the patients during dispensing. The pharmacists were to discuss any questions raised by the patient with a qualified practitioner [1]. With this regulation, pharmacists were reduced to only dispensing pre-synthesised medicinal products.

This period also saw transformation in curricula of pharmacy education across the US: pharmacognosy was transformed into medicinal chemistry, zoology to physiology, and galenical pharmacy to pharmaceuticals. New disciplines (pharmacology, biopharmaceutics and pharmacokinetics) were introduced as applied disciplines from other basic sciences. The decision to introduce these courses was based on the fact that new drug deliveries required pharmacists to have scientific background to understand and interpret literature of medicinal products which would continue to enter the market throughout a pharmacist's entire career. However, this created pharmacists that were overeducated and hence underutilised for what they knew [3].

Pharmacy from the Early 1970's to Present

The early 1970's witnessed rapid expansion of healthcare services and their consumption. Expensive new medicines and technologies became available. Professionalization and specialization of healthcare occupations took place, as well as proliferation of medical diagnoses for conditions that previously had no known treatments. Health insurance market and indemnity insurance also evolved. [1] During this period, pharmacists were viewed by the public as more of business men than healthcare providers. [3] Pharmacists were also viewed as an extension of manufacturers and wholesalers, owing to the rapid expansion of large, full-service chain pharmacies that sold other products besides medicines [1]. This stage of the pharmacy profession required pharmacists to be adequately trained in systems analysis, and also to possess management and communication skills that would promote their relationship with patients, physicians and other healthcare professionals [1]. Sadly, these attributes were lacking [4]. This prompted the addition of behavior and social sciences into the pharmacy curricula and participation in research about practice-related problems [5].

Pharmaceutical Care

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve patient's quality of life [6]. These outcomes are to (1) cure disease, (2) reduce or eliminate symptoms, (3) arrest or slow progression of a disease, (4) prevent disease or symptoms, and (5) normalize a physiological parameter.6 Pharmaceutical care can be achieved through three major functions which include: (1) identifying potential and actual drug-related problems or needs, (2) resolving the drug-related needs, and (3) preventing drug-related problems [6]. Drug-related problems or needs are can be classified under (1) indication, (2) effectiveness, (3) safety, and (4) compliance (Table 1) [6,7].

Category	Sub-category	Drug-related problem	Intervention	
Indication	Additional therapy needed	Untreated condition exists	Additional therapy Medical tests to confirm diagnosis,	
		Patient needs prophylactic or preventive therapy	Provide vaccinations if pending Provide prophylactic treatment	
		Synergistic therapy required	Provide appropriate additional therapy	
	Unnecessary drug therapy	Patient receiving medication without an indication	Stop unnecessary medication	
		Patient using recreational drugs	Manage addiction Provide appropriate withdrawal therapy	
		Pharmacological therapy not necessary	Provide appropriate non-pharmacological therapy	
		Therapeutic duplications	Stop additional unnecessary therapy	
		Using drug therapy to treat avoidable adverse effects	Manage drug therapy and avoid additional therapy	
Effectiveness	Wrong drug	Inappropriate dosage form	Provide an appropriate dosage form (consider efficacy, safety, patient factors and cost)	
		Medication contraindicated	Evaluate and consider risk/benefit ratio	
		Condition being treated refractory to treatment	Evaluate and appropriate medication	
		Medication not indicate for condition	Stop medication. Initiate appropriate medication	
		Current medication not the most effective	Stop current medication Initiate more effective medication (consider efficacy and safety)	
	Low dose	Prescribed dose not appropriate for the patient	Adjust the dose to provide therapeutic serum concentrations	
		Inadequate dosing frequency	Alter the dosing frequency based on the pharmacokinetic properties of the drug	
		Inappropriate duration of treatment	Alter duration of treatment based on the patient and condition being treated	
		Incorrect storage conditions might compromise medication efficacy	Counsel patient on appropriate storage condition for the specific medicine	
		Incorrect mode of administration	Design a mode of administration which optimizes the medicine's efficacy	
		Pharmacokinetic or pharmacodynamic drug interaction which alters medicine efficacy	Optimise therapy to minimizes drug-drug, drug-disease and drug-food interactions Increase dose of the drug whose serum levels are reduced by the interaction	
		Prescribed medicine has a narrow therapeutic index	Monitor serum drug concentrations to ensure they are in the therapeutic range for the patient	
		Patient factors render medication ineffective	Design appropriate regimen for non-modifiable factors (race, gender, age) Counsel patient for modifiable factors (smoking and alcohol use)	

Safety	Adverse drug reaction	Drug unsafe for patient	Adjust patient's medication based on history
		Patient allergic or intolerant to prescribed medication	Take comprehensive patient history Advise patient to always provide allergy history Advise patient to wear medical alert bracelets
		Incorrect dosage, route or mode of administration	Consider patient factors and design a dosage form which will deliver the drug to the intended site of action
		Dose increased or decreased too fast	Provide pharmacokinetic properties of the drug to prescriber if necessary
		Patient experiencing an undesirable effect	Monitor patient for any drug-induced and idiosyncratic responses
	High dose	Patient receiving a wrong dose	Individualise the dose for the patient
		Inappropriate frequency	Reduce frequency and monitor serum drug concentrations
		Inappropriate duration	Reduce duration to avoid toxicity
		Drug interaction results in increased serum levels of other medicines the patient is taking	Reduce the dose of the drug being potentiated Design another regimen which minimizes extent of the drug interaction
		Prescribed medicine has a narrow therapeutic index	Monitor serum drug concentrations to ensure they are in the therapeutic range for the patient
Compliance	Inappropriate compliance	Prescribed drug not available	Provide a therapeutically equivalent alternative
		Patient cannot afford the prescribed medication	Provide a cheaper therapeutic equivalent medicine with comparable effectiveness
		Patient cannot tolerate the prescribed medicine	Design a patient-friendly regimen
		Patient does not understand how to take the medicine	Educate the patient on how to take the medicine Provide illustrative material to patient
		Patient experiences unbearable side effects	Change to a medicine the patient can tolerate Provide supportive counseling
		Drug regimen too complex for the patient	Counsel the patient Provide fixed-dose combination (FDC) therapies
		Patient does not know what they are taking the medicine for	Counsel patient
		Patient does not believe in the therapeutic approach	Explain both orthodox and allopathic therapies and implications of each

Table 1: Pharmaceutical care tool for Identifying, resolving and preventing drug-related problems or needs.

Clinical Pharmacy

Clinical Pharmacy was born in the 1960's to incorporate drug use control and also to promote the pharmacists' role as therapeutic advisors [1]. The six-year Doctor of Pharmacy (Pharm D) degree was also introduced in the US with the sixth year being devoted mostly to therapeutics or disease-oriented and patient-focused practice. A number of colleges of pharmacy began to offer the Pharm D degree across the US in the 1970's, 1980's and early 1990's [1]. Graduates with the Pharm D degree secured employment as clinical pharmacists in hospitals and they carried out less dispensing but spent more time on determining drug doses using the pharmacokinetic parameters of the drugs, therapeutic drug monitoring, and providing drug information [1]. Eventually, the colleges of pharmacy phased out the Bachelor of Pharmacy program and adopted the six-year Pharm D program as the only entry-level qualification into the profession in the US [8].

Pharmaceutical Care and Clinical Pharmacy in South Africa: Is it possible?

In the 1980's, in South Africa, pharmaceutical care expanded into what is currently known as primary care drug therapy (PCDT), a course through which pharmacists are certified to prescribe and dispense schedule 3-4 medicines. Primary care drug therapy later faced stiff resistance from the medical profession after being regarded as "boundary encroachment," with claims that PCDT extended the boundaries of pharmacy practice into the territory of the medical profession [9]. Nevertheless, PCDT was implemented but only to serve under-served, rural parts of South Africa.

A few issues and proposals regarding the provision of pharmaceutical care were raised by Helper and Strand in 1990 [6]. They mentioned four criteria which must be met before pharmacists can be granted the authority to provide pharmaceutical care and before pharmacists can accept that responsibility: (1) the provider must possess adequate knowledge and skills in pharmaceutics and pharmacology, (2) the provider must be able to mobilise the medicine distribution system through which medicine use decisions are implemented, (3) the provider must be able to develop a relationship with the patient and other health professionals who are needed in the provision of pharmaceutical care, and (4) there must be a sufficient number of the professionals to serve the society. They also noted that pharmaceutical education was better placed than any other program to provide enough professionals to meet the need for pharmaceutical care. Does South Africa meet these requirements?

Skills and Knowledge

In South Africa, there are nine universities providing a four-year pharmacy degree at an undergraduate level. These universities include: Nelson Mandela Metropolitan University (NMMU), North-West University (Potchefstroom Campus), Rhodes University, Sefako Makgatho Health Sciences University (SMU), Tshwane University of Technology (TUT), University of Limpopo, University of KwaZulu-Natal (Westville Campus), University of the Western Cape (UWC) and the University of Witwatersrand [10]. The four major fields of training towards attaining an undergraduate degree in pharmacy in South Africa are: Pharmacy practice, Pharmacology, Pharmaceutics and Pharmaceutical chemistry. These four fields of study are aimed at providing adequate skills and knowledge to meet criterion one listed above as "adequate knowledge and skills in pharmaceutics and pharmacology".

There has been an introduction of clinical pharmacy training at three universities in South Africa in the past two decades. These include the University of Witwatersrand (1993: M.Sc. (Med) Pharmacotherapy), the former University of Limpopo's Medunsa Campus (currently SMU) (1993: Master of Pharmacy [Clinical Pharmacy]), and Rhodes University (2004: Doctor of Pharmacy [Pharm D]). The curricula of these programmes were detailed in the article "The State of Clinical Pharmacy in South Africa: Current and future Perspectives" [11].

South Africa, however, does not have an established "scope of practice for clinical pharmacists," and as such, pharmacists trained in these programs end up performing activities that fall under the present "scope of practice of pharmacists" as stipulated in the Pharmacy Act 53 of 1974, [12] which does not put any exclusive emphasis on clinical pharmacy. This challenge is compounded by the shortage of pharmacists and largely by the lack of professional recognition of clinical pharmacists as specialists. Although the Department of health has implemented medicine procurement reforms, there are still challenges regarding medicine availability in public health facilities in South Africa and hence, drug procurement, distribution and dispensing takes majority of the pharmacists' time at work. Hepler and Strand [6] noted that "Pharmaceutical services like pharmacokinetic dosing, therapeutic monitoring, and drug information may extend functions, legitimate competence, and generally enhance professional status, but unless they are carried out in the context of professional responsibility....., they cannot constitute a professional role." Major decisions, therefore, need to be made in order to recognize clinical pharmacy as a specialty. Williams also stated that "if we really intend to re-professionalize the practice and implement the principles of pharmaceutical care, then we must give a high priority to obtaining enabling legislation or rules that will permit every pharmacist to best utilize his/her extensive pharmaceutical knowledge [9-13]".

Availability of a medicine distribution system through which medicine use decisions can be implemented

Despite facing challenges in the medicine availability in the public health facilities, South Africa has a well-established medicine procurement and distribution system. Each of the nine provinces has a medicines depot which procures medicines for all the facilities in that province from the national contracts. Facilities can order medicines from the depot, directly or indirectly (via the depot) from the companies (suppliers, contract suppliers and manufacturers). There are Pharmacy and Therapeutics committees (PTCs) at four levels in the medicine supply chain. These include: (1) facility level (hospital: sub-district, regional or tertiary), (2) district level, (3) provincial level and (4) national level. Decisions regarding medicines usage are escalated from facility to national PTCs once every three months. Final decisions are communicated through national and provincial circulars to all facilities. This, therefore, provides opportunities for providers of the pharmaceutical care service to participate in a well organized medicine distribution system through which medicine use decisions are implemented as proposed by Helper and Strand [6].

Relationships of pharmacists with patients and other health professionals

Although pharmacists are custodians of medicines, drug therapy is too complex and one professional cannot manage the entire process alone [1]. The procurement process alone for example requires pharmacists, accountants and supply chain managers, whereas prescribing and administration requires nurses, doctors and pharmacists. Hence the success of the pharmaceutical care process depends on the pharmacists' relationships with other professionals. However, one attribute that makes the pharmacists champions of this chain is the element of pharmaceutical care which Hepler [2] defined as a "covenantal relationship between a patient and a pharmacist in which the pharmacist performs drug use control functions (with appropriate knowledge and skills) governed by the awareness of and commitment to the patient's interest." This means that the pharmacist accepts responsibility for the provision and outcomes of medicine use.

Availability of Human Resources

There are 15,639 registered pharmacists in South Africa [14]. This gives a national average ratio of 1 pharmacist for every 3,514 South Africans, currently estimated to be 54.96 million [15]. However, the distribution (over 70%) of the registered pharmacists is skewed towards the private sector which serves approximately 20% of the population, giving a ratio of 1 pharmacist for 1,004 people. This implies that less than 30% of the workforce is left to the public sector which serves approximately 80% of the population. Hence, the pharmacist to patient ratio in the public sector (1 pharmacist for every 9,324 people) is even much lower than the national average. The World Health Organization (WHO) recommends a minimum of 44 pharmacists for every 100,000 people (about 1 pharmacist for every 2000 people). The low ratio of pharmacists per patient increases workload and compromises the quality of care: patients wait longer to have their prescriptions filled and time for therapeutic drug monitoring and pharmaceutical care is very limited. This shortage of pharmacists is somehow a pseudo-shortage because some facilities have unfunded posts for pharmacists, which cannot be occupied unless funds are made available. There have been claims that the department of health is currently unable to hire healthcare professionals due to shortage of funds in the healthcare budget [16].

The past few decades in South Africa have seen efforts being made to alleviate this shortage of pharmacists including statutory establishments and amendments. For example, the Medicines and Related Substances Act 101 of 1965 as amended (Medicines Act) [17] and the Nursing Act 33 of 2005 (Nursing Act), [18] both authorize nurses to dispense medicines; if there is no qualified pharmacist or dispensing doctor. Section 38A of the Nursing Act 50 of 1978 [19] and Section 56(6) (d) (iii) of the Nursing Act 33 of 2005 [18] also authorize nurses to keep, prescribe and dispense medicines in the absence of a pharmacist or medical practitioner. The purpose of allowing nurses to dispense was to address the shortages of personnel providing dispensing services and enhance access to health services, for the benefit of all citizens [20].

Involvement of Government

Inevitably, the government needs to be involved in both training and deployment of skilled personnel. The South African government has made several commitments to train pharmacists. One of these was establishment of provincial department of health bursaries for qualifying matriculates to enroll at universities and obtain qualifications in pharmacy. These bursaries require the bursary holder to make a commitment to work for the same provincial department of health for a period not less than the number of years an individual received the study bursary.

The government also established pharmaceutical community service which requires every trained pharmacist who intends to register to practice pharmacy in South Africa to serve in the public health sector for a minimum period of 12 months (36 months for non-South African citizens) before registering with the SAPC to practice independently. The main aim of pharmaceutical community service is to avail pharmacists to the underserved areas, especially the rural parts of the country. This strategy worked well regarding availability and retention of pharmacists in the public health sector in the past years, until recently when a number of applicants could not be employed due to lack of funded community service posts [16].

Perhaps the next crucial step required of the government is to amend the regulations relating the practice of pharmacy in South Africa. The South African Pharmacy Council has submitted to the National Department of Health of South Africa, a "Scopes of Practice and Qualifications for Specialist Pharmacists" in South Africa. This document has been gazette and the approval thereof will pave the way for pharmacists to train and become clinical pharmacy specialists or clinical pharmacists. The approval will also pave way for creation of posts for clinical pharmacists in the occupation specific dispensation (OSD) ranks. This, in my opinion will most definitely be a motivating factor towards specialization in clinical pharmacy. At the moment, remuneration of pharmacists is based on the number of years of experience, not on specific skills which often require advanced training in a specific field. Pharmacists therefore are not motivated take up postgraduate studies in pharmacy to specialize, if they will be earning the same salary without the extra qualifications.

Conclusion

Pharmacy has come a long way from being product-focused to being patient-centered. In South Africa, various establishments have been made to alleviate the shortage of pharmacists but, much remains to be done to establish a sound and recognisable clinical pharmacy workforce. Clinical pharmacy needs to be recognized as a specialty in order to attract trainees. Training in clinical pharmacy needs to be expanded, followed by creation of posts for clinical pharmacists at every hospital. This will pave way for pharmacists to get more involved and apply clinical pharmacy principles such as developing patient care plans, therapeutic drug monitoring, and clinical pharmacokinetics, and to improve therapeutic outcomes.

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