INTERNATIONAL PERSPECTIVES ON PHARMACY PRACTICE

Health Care and Pharmacy Practice in South Africa

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INTRODUCTION

Couth Africa is a large (about 1.2 million km²), upper middle Jincome country located at the southern tip of the African continent. The 2014 midyear estimate of the total population was just over 54 million, of whom 80.2% self-identified as Black Africans.1 South Africa underwent a fundamental political transition to democracy in 1994, with the demise of the racially segregated apartheid system. In the years since then, there has been an ongoing process of reform in all areas, including in relation to the organization and delivery of health care. The organization, financing, and delivery of pharmaceutical services have also been subject to significant changes in this period. This paper describes the background and current position of pharmacy in South Africa, with particular reference to reforms that are still underway and those that are anticipated. In many ways, and in particular with regard to the delivery of hospital pharmacy services, pharmacy reform can still be regarded as a work in progress. The paper is arranged according to the "building blocks" outlined in the World Health Organization's Health Systems Framework.²

HEALTH SYSTEM LEADERSHIP, GOVERNANCE, AND FINANCING

The South African health system still shows many of the design features of its fragmented and contested past.^{3,4} In the colonial and apartheid eras, health care was provided separately to each of the ethnic groups in the country. Separate health facilities were provided for Black Africans, Whites, those of mixed race (referred to locally as "Coloured"), and those descended from South Asian immigrants (referred to locally as "Indian"). To add to the fragmentation that this approach created, the apartheid policy also led to the creation of quasi-independent "bantustans" for different tribal or language groups within the Black African community. By 1994, four of the bantustans had been given nominal independence, but other "homelands" within the borders of South Africa operated their own public sector health

services. To further complicate matters, curative health services in the public sector were organized on a provincial basis (for the 4 provinces that had united in 1910 to form the Union of South Africa), but preventive and promotive health was financed and delivered by the Department of National Health and Population Development. As Coovadia and others³ have summarized, "By the end of the apartheid era, there were 14 separate health departments in South Africa ..., health services were focused on the hospital sector, and primary level services were underdeveloped."

Since the implementation of South Africa's democratic constitutional order, and as outlined in the new National Health Act (Act 61 of 2003), a degree of consolidation has occurred. However, the system remains complex. According to the Constitution, health is a concurrent competence of both the national and provincial spheres of government. In addition, local governments (municipalities) have responsibility for municipal health services, which are predominantly restricted to environmental health issues. Therefore, while there is a National Department of Health, along with a National Minister of Health, there are also 9 provincial departments of health. Overall policy guidance is provided from the national sphere, but delivery of health services is the responsibility of the provincial departments. This arrangement is also mirrored in the financing of public sector health services. Provinces are funded from the national fiscus on the basis of an equitable-share approach (based on population, with adjustment for prior levels of development to advance equity) and then determine their own health budgets. Within the provinces, the public health sector is organized by districts. Overall, there are 52 health districts across the 9 provinces.⁵ The public sector comprises 16 tertiary hospitals, 698 specialized hospitals (such as psychiatric or tuberculosis hospitals), 55 regional hospitals, 254 district hospitals, 282 community health centres, and 3075 primary health care clinics.⁶ Together, the public sector hospitals provide almost 87 000 beds.

However, there is also a parallel private health care delivery system. Of the total population, about 8.6 million (17%) are privately insured (i.e., are beneficiaries of a medical scheme). For permission to reprint multiple copies or to order presentation-ready copies for distribution, contact CIHP at cjhpedit@cshp.ca

Beneficiaries of medical schemes do not generally access health care through public sector facilities. Instead, they use the 216 private hospitals, which have a total of just over 31 000 beds. There are 90 separate medical schemes in operation, all of which offer a range of benefit options. In 2013, the total benefits paid amounted to ZAR 103.3 billion7 (at the time of writing, in late 2015, CAD\$1.00 = ZAR 9.68). The average spend per beneficiary per annum was therefore ZAR 12 859. This contrasts with the ZAR 2 857 per person expended in the public sector (2012 data, calculated as the total of provincial expenditure per uninsured population).8 Overall, South Africa spent 8.3% of gross domestic product on health in 2013: 4% in the public sector and 4.3% in the private sector. Put differently, approximately 40% of health care in South Africa is financed through general tax revenues, about 45% through private medical schemes, and the balance (about 14%) through out-of-pocket payments.9 This division of expenditure, and the spend as a percentage of gross domestic product, has remained relatively constant in recent years. Medicines accounted for 16% of all expenditure in the private sector in 2013. Expenditure per beneficiary on medicines did not change markedly in the private sector between 2004 and 2013, after inflation was taken into account, which reflects the overall impact of a range of health policy interventions, including mandatory offer of generic substitution, regulated annual percentage increases in factorygate prices, maximum dispensing fees, and the application of a variety of managed care measures.

South Africa's post-apartheid Constitution entrenched the right of access to health care services, but with an important caveat.¹⁰ This critical socioeconomic right is to be progressively attained, within the constraints of available resources. The end of apartheid in 1994 signalled a fundamental change in the South African health care system. The focus after 1994 was on equity and access for all. A move toward services at a primary health care level, as evidenced by the building of new primary health care clinics in rural and underserved areas, was a key mechanism for providing accessible health care to all South Africans.¹¹

HEALTH INFORMATION AND RESEARCH

Given the degree of fragmentation described above, it is not surprising that a well-functioning and comprehensive health information system has yet to be attained in South Africa. In the public sector, the District Health Information System provides data on the provision of services through clinics, community health centres, and hospitals. Although one set of annual health statistics, for 2012, were issued,¹² these data have not been updated, and the most comprehensive dataset remains that reported in the *District Health Barometer*⁵ and the annual *South African Health Review*,⁸ both published by the Health Systems Trust. Data on the provision of health care services in the private sector are collected by each medical scheme or its contracted administrator, but these data are not aggregated in any way, nor are they integrated with the district health data for the public sector. Where data are based on vital statistics registration (such as births and deaths), they then more comprehensively represent the entire population, including both insured and uninsured.

For an African country, South Africa has a low total fertility rate (2.3 children per woman per lifetime).⁶ Life expectancy at birth has increased to 61 years, from 52 years in 2005. This increase in life expectancy has been attributed to the decrease in the number of AIDS-related deaths (from 51% of all deaths in 2005 to 31% of all deaths in 2014), largely because of improved access to antiretroviral therapy.1 Additionally, there has been a fall in the infant mortality rate, from 58 deaths per 1000 live births in 2002 to 34 in 2014. South Africa, however, still faces a significant burden of disease, associated with communicable and noncommunicable diseases, as well as injuries. South Africa is one of the countries most affected by tuberculosis (more than 1000 prevalent cases per 100 000 population), with significant numbers of drug-resistant cases. South Africa has the largest number of people living with HIV (5.8 million) in the world, as well as the largest antiretroviral treatment program (almost 3 million patients on treatment).¹

HEALTH WORKFORCE

South Africa faces an absolute shortage of health care professionals, but also a maldistribution of the available health workforce, between the public and private sectors and between urban and rural settings. In 2013, of a total of 39 847 medical practitioners (including 14 021 specialists) registered with the Health Professions Council of South Africa, only 13 614 (34%) were employed in the public sector.⁶ Similarly, of the 129 015 professional nurses registered with the South African Nursing Council in 2013, only 63 833 (49%) were employed in the public sector.⁶

Pharmacists in South Africa are registered by a national regulatory body, the South African Pharmacy Council, after completing a 4-year undergraduate degree, a year of preregistration experience (internship), and a year of community service in a public sector facility. All accredited institutions now offer a 4-year Bachelor of Pharmacy degree (BPharm), but a 4-year diploma was offered in the past. There are at present 8 accredited universities offering the BPharm degree in South Africa, with one of these schools now being divided into 2 separate institutions. Although the total number of pharmacists on the register has increased by only 16% since 2007, the number employed in the public sector has increased by 147% over the same period (Table 1). The driving force behind this shift has been the improved conditions of service offered in the public sector, where salaries are now very competitive with those offered in the private sector. Nonetheless, the number of public sector pharmacists per 100 000 public sector-dependent population is less than half what would be expected in a typical middle-income country.¹³

Table 1. Pharmacy Workforce in South Africa⁶

	Category; No. of Pharmacist			
Year	Total Registered	Employed in Public Sector		
2007	11 547	1 830		
2008	11 905	1 853		
2009	Data not available	1 835		
2010	12 218	2 966		
2011	12 460	3 550		
2012	13 003	3 901		
2013	Data not available	4 224		
2014	13 364	4 516		

It is difficult to accurately determine where pharmacists are employed at any given time, because of considerable mobility, a large *locum tenens* workforce, and an unknown number who retain registration but are either not practising or have left the country. As of 2015, there were 13 416 registered pharmacists in South Africa.¹⁴ Of these, 60% were female, with just over 50% selfidentifying as white, 20% as Indian, and 20% as Black African. The demographic characteristics of the pharmacy student population more accurately reflect the country's demographic distribution, with the majority being Black Africans (56.9%).

There are 7 categories of pharmaceutical institutions (practice types) recorded by the South African Pharmacy Council (Table 2).¹⁴ The majority (68.3%) are community pharmacies, which are all in the private sector. Institutional pharmacies are those located within hospitals and community health centres, but also include pharmacies located within clinical research units. They are recorded separately for the public and private sectors. Wholesale pharmacies include the provincial stores in the public sector, but are predominantly located in the private sector. All manufacturing pharmacies are in the private sector. All academic institutions are located within public universities. The small number of consultant pharmacies do not provide medicines, but only offer consultancy services, predominantly in the private sector.

In addition to registered pharmacists, pharmacist interns, and those completing the compulsory year of public sector service, the pharmaceutical workforce is supplemented by a number of categories of support personnel. At present, this

 Table 2. Pharmaceutical Institutions (Practice Types)

 Recorded by the South African Pharmacy Council*

Type of Pharmacy	No. (%) of Pharmacies (<i>n</i> = 4480)		
Academic institution	9	(0.2)	
Community pharmacy	3059	(68.3)	
Consultant pharmacy	11	(0.2)	
Private institution	272	(6.1)	
Public institution	645	(14.4)	
Manufacturing pharmacy	257	(5.7)	
Wholesale pharmacy	227	(5.1)	

*Data from the South African Pharmacy Council website.¹⁴

support cadre comprises learner basic pharmacist's assistants, basic pharmacist's assistants, learner post-basic pharmacist's assistants, and post-basic pharmacist's assistants. There are currently just over 15 000 registered pharmacy support personnel in South Africa.¹⁵ Pharmacist's assistants are currently trained in health facilities, using materials provided by accredited providers. A new cadre of pharmacy technicians has been created, with full-time training at accredited tertiary institutions.¹⁵ The first entrants to the new registers have recently qualified.

Although South Africa has had registers for 2 cadres of specialist pharmacists (pharmacokineticists and radio-pharmacy specialists) for several years, the number of registered specialists has been very low, in part because entry to the register has required the completion of a suitable master's degree. A proposal to update the existing specialist categories and create new categories (specialist clinical pharmacist and public health pharmacy and management specialist categories) has been planned by the South African Pharmacy Council, but not yet actioned.¹⁶ Recognition of existing qualifications that could meet the minimum requirements and procedures for recognition of prior learning are however lacking. These proposed new qualifications are also based on full-time postgraduate training, and not on the completion of residencies or board certification, which can be completed on a part-time basis, as has been done elsewhere.¹⁷ The scopes of practice of pharmacists and specialist pharmacists are not mutually exclusive and, at present, where advanced practices are implemented, these are offered by pharmacists with additional skills gained on the job or via postgraduate programs that may not necessarily lead to specialist registration. A number of Master of Pharmacy (MPharm) programs are offered by universities, as well as one postbaccalaureate Doctor of Pharmacy (PharmD) program. Graduates of these programs work in a variety of settings, including public and private sector hospitals, medical scheme administrators, pharmacy benefit management firms, provincial departments of health, and the National Department of Health. They are involved in the provision of clinical pharmacy services and policy development (including the development and implementation of standard treatment guidelines, essential medicines lists, and reimbursement processes).

The typical daily activities of both public and private hospital pharmacists are usually dominated by medication dispensing and stock control (at both a ward and an institutional level). Other daily tasks will vary by institution and may include activities such as extemporaneous compounding, cytotoxic and other sterile admixture services, ward rounds, patient education, training of health care professionals, and medication safety monitoring (medication error and pharmacovigilance systems). Pharmacokinetic advisory services are poorly developed, but increasing attention is being paid to antimicrobial stewardship programs, particularly in private hospitals. Dedicated ward pharmacists have been deployed in some private hospitals. Public sector hospital pharmacies also carry a large ambulatory care load, which occupies much staff time.

In South Africa, prescribing privileges are ordinarily restricted to medical practitioners and dentists. However, provisions for exceptional access are available to a range of nonmedical prescribers. In particular, the Medicines and Related Substances Act (Act 101 of 1965), which governs the registration, marketing, and use of medicines and medical devices, allows for specific medicines to be prescribed by practitioners other than medical practitioners and dentists. Lists of medicines have been developed for dental therapists, optometrists, and 3 classes of emergency personnel. Lists still need to be finalized for podiatrists. The process has yet to commence for various categories of specialist nurse practitioners,18 but there is also an exceptional process available through the Nursing Act (Act 33 of 2005), which allows for nurses employed in the public sector and designated private facilities to be issued with permits to prescribe and dispense a limited list of medicines. What is missing entirely, however, is legislative enablement for dependent prescribing, akin to patient group directives. Such a legislative instrument would be needed to enable the forms of collaborative practice that are common in many other countries, where pharmacists are able to continue management of a patient's medicine therapy after an initial diagnosis and prescription by a medical practitioner. Therefore, while pharmacists in South African hospital practice may contribute to antimicrobial stewardship programs (including switches from IV to oral administration), provide pharmacokinetic advice (therapeutic drug monitoring), or service anticoagulant clinics, they are unable to alter doses or order laboratory tests on their own.

HEALTH SERVICE DELIVERY

The majority of pharmacists in South Africa practise in community pharmacies, which either are pharmacist-owned (independent) or form part of pharmacy chains. These pharmacies are predominantly located in urban areas, where they service the insured (medical scheme beneficiary) population. To some extent, they also provide pharmacist-initiated therapy to those who can afford to buy nonprescription medicines out-of-pocket. Community pharmacies in South Africa provide a full range of prescription and nonprescription medicines. In terms of the Medicines and Related Substances Act (Act 101 of 1965), there are 2 categories (Schedule 1 and 2) of pharmacist-only initiated medicines, only one of which (Schedule 1) can be advertised directly to the public. An additional category of medicines (Schedule 0) can be sold in any outlet (including supermarkets or general dealers) and advertised to the public. Prescription-only medicines are listed in Schedules 3 to 6 and cannot be advertised directly to the public. Typical community pharmacies also provide a full range of toiletries, cosmetics, and other nonhealth products.

Hospital pharmacists working in the private sector are predominantly employed by 3 hospital groups that dominate this market, with a minority working in smaller, independent hospitals. Larger private hospitals also provide a full community pharmacy service, sometimes from a separate pharmacy on the same premises. Private hospitals do not usually provide medicines for ambulatory care and are restricted to a limited quantity of discharge medicines for those leaving the hospital. Like private sector community pharmacies, private hospitals are highly computerized, allowing for the individual labelling of medicines for all patients. Electronic patient medication histories are commonly maintained, but integration with other hospital systems is not yet common. Computerized physician order entry and decision support software are very rarely encountered. There are a handful of "paperless" hospitals in the private sector. Private hospital services are usually offered over extended hours (but less than 24 h/day) and are restricted on weekends and holidays. Although larger private hospitals are likely to have the means to allow for some aseptic compounding, none offer full IV admixture services, and none operate on a unit-dose system.

In the public sector, pharmacists work in a wider variety of health facilities, including hospitals of variable size and complexity, larger community health centres, medical stores, and district, provincial, and national offices. In contrast to private hospitals, public sector hospitals are more likely to rely on paper-based systems, rather than computerized patient records. There is one public sector hospital with a computerized physician order entry system, but it has no decision support elements. All public sector hospitals rely to a greater extent than private hospitals on extensive ward stock, and therefore a greater proportion of medicines on wards that are not individually labelled for specific patients. No public sector hospitals operate on a unit-dose basis, and none operate full IV admixture services, although larger, tertiary hospitals are likely to have limited aseptic compounding and chemotherapy reconstitution services.

The private sector, community, and hospital pharmacies procure medicines from a range of pharmaceutical wholesalers and distributors, which are in turn supplied by manufacturers and importers. There is very limited local production of active pharmaceutical ingredients in South Africa, but there are extensive facilities for producing finished pharmaceutical products from imported active pharmaceutical ingredients or packaging imported finished pharmaceutical products. The South African Medicines Control Council (MCC) has licensed 259 entities as manufacturers, importers, and/or exporters of medicines, secondary packers, or testing laboratories (or in at least one of these categories).¹⁹ Of these, 77 entities are listed as manufacturers of medicines. The list includes locally registered subsidiaries or offices of both transnational pharmaceutical firms and international generic pharmaceutical manufacturers. In addition, the MCC lists 194 pharmaceutical wholesalers. In the public sector, there are 11 provincial medical stores, which supply hospitals,

community health centres, and clinics. Increasingly, the public sector is using direct delivery from manufacturers and importers to health facilities, bypassing the medical stores.

ACCESS TO MEDICINAL PRODUCTS, VACCINES, AND TECHNOLOGY

All medicines on the South African market require registration (marketing authorization) from the MCC, which is a member of the Pharmaceutical Inspection Co-operation Scheme. The MCC is a mature and stringent national medicines regulatory authority, with growing links to stringent authorities in other jurisdictions. At present, the MCC is embarking on the regulation of medical devices and is also addressing the appropriate regulation of complementary medicines, based largely on the systems in place in Canada and Australia.

Access to medicines in the private sector is extensive, within the constraints of medical scheme reimbursement policies and benefit designs. Accordingly, there is relatively unfettered access to a wide range of branded and generic medicines, many of which incur limited or no copayments. In the public sector, access is more constrained and is limited to the specific products procured on competitive tenders and listed on the National Essential Medicines List. All medicines are provided free of charge at primary care facilities to those without private insurance. User fees at public sector hospitals are means-tested, and there is no specific charge for medicines (i.e., fees are for a comprehensive service per day, including all services). Maximum charges are also modest, even for those who are employed but uninsured. All antiretroviral medicines are provided free of charge to public sector-dependent patients, for example. The Essential Drugs Programme was established in accordance with the National Drug Policy of 1996, which had the aim "to ensure an adequate and reliable supply of safe, cost-effective [medicines] of acceptable quality to all citizens of South Africa and the rational use of [medicines] by prescribers, dispensers and consumers."20 The Essential Drugs Programme facilitates the development and dissemination of standard treatment guidelines and essential medicines lists for different levels of care. There are 3 sets of standard treatment guidelines and essential medicines lists (for primary care, adult hospital, and pediatric hospital levels of care), as well as a tertiary/quaternary medicines list. There are currently just over 1200 items on the consolidated National Essential Medicines List (including different strengths and pack sizes). An Expanded Programme on Immunization offers a comprehensive range of vaccines, including rotavirus vaccine, pneumococcal conjugate vaccine, and human papillomavirus vaccine, free to all public sector-dependent patients.

FUTURE DIRECTIONS

South Africa is in the process of implementing universal health care coverage in the form of National Health Insurance,

with the aim of bridging the gap between public and private health care.^{21,22} Implementation is expected to take up to 14 years, but even the first steps of this process have been protracted. Moving to a single financing system will pose significant challenges for the entire system of medicines selection, procurement, distribution, and use, in which pharmacists will play a central role. Potentially, both specialist clinical pharmacists and pharmacy policy specialists will be key to the new health system, its design, and its operation. Collaborative practice options have as yet not seen as much attention as they deserve. This is not merely a question of task shifting, making do with what resources are available, but an option that could deliver both efficiency gains as well as effective solutions to the challenges of improving the responsible use of medicines.

CONCLUSION

South Africa's health care system has experienced a series of fundamental transformations since the end of the apartheid era. The provision of equitable access to quality health care for all South Africans, a fundamental constitutional right, remains a challenge. South African health policy is directed toward the delivery of safe, effective, and cost-effective health care services. Some progress has been evident, with clear improvements in life expectancy at birth and the infant mortality rate. The South African National Drug Policy, albeit somewhat outdated, continues to inform the transformation of the pharmaceutical system and the contribution that is demanded from pharmacists in all sectors of practice. As the process of change to universal health care unfolds, pharmacists will need to play a crucial role in managing system and policy development, to ensure the provision of equitable patient care and access to essential medicines across all sectors.

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Competing interests: Andy Gray is a member of the Medicines Control Council and the National Essential Medicines Committee, both of which are ministerially appointed structures involved in medicines-related issues (medicines regulatory authority and public sector medicines selection body). He is also a member of the South African National Essential Medicines List Committee, the World Health Organization (WHO) Expert Panel on Drug Policies and Management, the WHO Guideline Steering Group for the Four Cornerstones of Family Planning Guidance, and the Joint United Nations Programme on HIV/AIDS (UNAIDS) Scientific Expert Panel. No other competing interests were declared.

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ON THE FRONT COVER



River Valley Road West Edmonton, Alberta

CSHP member Gerda Tawfik (Clinical Pharmacist in the Pediatric Intensive Care Unit of

Stollery Children's Hospital, Edmonton, Alberta) took this photograph with her iPhone while looking out at the North Saskatchewan River in Edmonton's river valley. Gerda and her husband were walking along the shared biking-walking path on River Valley Road West. The low lighting at sunset and the reflections and shadows on the snow caught the photographer's eye.

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