Tied up in knots …. or an essential safety net?

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Introduction

There is a strong autarkical tendency amongst pharmacists, perhaps related to their historical origin as sole proprietors and solo practitioners. This tendency leads to a marked resistance to the imposition of detailed standards of practice, and a characterisation of such efforts as needlessly interventionist, as disregarding the professionalism that is expected of pharmacists, and as yet more evidence of an over-bearing "nanny state".

This tendency is, of course, not restricted to pharmacists. Many other health professionals resist what they see as impositions from "outside", be that from medical scheme administrators, managed care firms, learned societies, guideline developers, or regulators.

This article proposes a different approach and motivates for a concerted effort by SAAHIP to contribute to the strengthening of Good Pharmacy Practice standards in South Africa, specifically related to hospital pharmacy.

The link between variability and quality

If it is accepted that high quality clinical services should be those that are clearly based on the best available evidence, then it should follow that variation from those standards is undesirable – that variation (or at least excessive variation) is analogous with poorer quality of care. This principle is well-established in clinical medicine, and has underpinned the development of evidence-informed clinical practice guidelines. However, it is also been shown that the reasons for variation in clinical practices are diverse and complex.[1] They can be traced to personal beliefs and education background, to organisational factors such as access to available infrastructure and equipment, and to systemic factors, including the design of remuneration systems. Nonetheless, it is accepted that evidence of variation indicates that "some patients with similar diagnoses, prognoses and demographic status receive different levels of care, depending on when, where and by whom they are treated, despite agreed and documented evidence of "best practice"".[1] Put simply, they receive poorer quality care than they deserve.

What may be less evident to pharmacists is that the same principles can apply to the full range of pharmacy professional activities, be those logistic, distributive, cognitive or clinical in nature.

Health systems re-engineering

As South Africa prepares for the introduction of Universal Health Coverage (UHC) in the form of National Health Insurance (NHI),[2] one of the key enabling interventions has been the creation of the Office of Health Standards Compliance (OHSC). The OHSC is an independent structure, outside of the Department of Health, with the specific mandate to monitor compliance with norms and standards for the provision of health services in both the public and private sectors.[3]

The OHSC has already embarked on the development of some of these necessary norms and standards, either as guidelines or as draft regulations.[4,5,6,7] The focus to date has been on the physical infrastructure of health facilities. The draft regulations published for comment in February 2015 are intended to apply to all public sector hospitals, clinics and community health centres, as well as all private sector acute hospitals and primary health clinics.[7] However, where they touch on pharmaceutical issues, the drafts are vague and poorly drafted. For example, draft sub-regulation 32(2)(b) states that a health establishment must "Ensure that all medicines are in stock, in accordance with the essential medicines list or applicable formulary". There is as yet no single nationally mandated Essential Medicines List that is applicable in both the public and private sectors. In time, an NHI reimbursement list may provide such an instrument. However, the standard set might still be vague and inappropriate for a wide variety of health establishments in both sectors.

Other documents in effect in the public sector are also lacking in detail regarding the provision of comprehensive pharmaceutical services. The National Core Standards for Health Establishments in South Africa have focused largely on medicines availability, rather than on the quality of pharmaceutical services.[8] The key standards are expressed as follows:

- Pharmaceutical services are licensed and are supervised by a registered pharmacist.
- Medicines and medical supplies are in stock and their delivery is reliable.
- Stock levels and storage of medicines and medical supplies are managed appropriately.
- Medicines are prescribed according to treatment guidelines and patients are educated to understand how and when to take them.
- Reactions to drugs or severe side effects are reported and the patient is properly cared for.

Each of these standards is unpacked as a series of "criteria". One of these states that "Health professionals can access medicines when required urgently after hours". Pharmacists who practise in hospitals will immediately identify this as a critical issue, on which there is little guidance and even less clarity.

Good Pharmacy Practice – a good start, but not enough

The 4th edition of the Good Pharmacy Practice (GPP) standards was published by the South African Pharmacy Council (SAPC) in 2010.[9] Since then, a number of amendments have been published for comment,[10] and others have been issued in final form.[11] However, while the GPP standards are detailed in some areas (notably in relation to the provision of emergency post-coital contraception), they are lacking in specificity in other areas. Like the Medicines and Related Substances Act (Act 101 of 1965), the GPP standards seem to be more easily applied to community pharmacy practice than they are to hospital pharmacy practice. Section 1.3 of GPP deals with "Minimum Standards relating specifically to Institutional Pharmacies". Apart from stating that the general standards for premises, facilities and equipment (1.2.1 to 1.2.13) apply to all pharmacies, the hospital-specific entries are minimalistic. Standards for services are listed in section 2.4, and here some more detail is provided. However, even when describing the standard for services provided to "wards departments, theatres, clinics (WDTC) and other outlets", only the most basic principles are stated: "Distribution of medicines within a hospital/institution must take place under the direction and control of a pharmacist and must be in accordance with Regulation 36 of the General Regulations published in terms of the Medicines Act".

The GPP thus relies on the subordinate legislation issued in terms of the Medicines Act. In that regard, almost the only recognition that hospitals represent a more complex practice setting is provided by General Regulation 36: "The responsible pharmacist or any other person licensed in terms of section 22C(1)(a)of the Act shall supervise the safety, security, purchasing, storage, and dispensing of medicines in a hospital". The reference is therefore circular in nature, and provides little guidance on how to meet the required standard.

Critically, while private sector hospitals may have access to more developed IT infrastructure than their public sector counterparts, such IT systems have not always been devised with GPP or the quality of pharmaceutical services in mind.

International precedents

There are excellent examples in other jurisdictions of pharmacists, and in particular hospital pharmacists, harnessing their collective strength to create and disseminate appropriate practice standards. The American Society of Health-System Pharmacists has a long history of developing policy positions and guidelines.[12] ASHP have justified the need for such guidelines by pointing to "changes in health care and … shifting influences from regulatory, accrediting, risk-management, financing, and other bodies". ASHP also notes that such documents must "evolve because of advances in technology, new knowledge from research, and lessons from experience". The Society of Hospital Pharmacists of Australia (SHPA) has produced a set of standards applicable to their setting,[13] as have the International Society of Oncology Pharmacy Practitioners (ISOPP).[14] At an international level, the updated Basel Statements produced by the Hospital Pharmacy Section of the International Pharmaceutical Federation (FIP) provide core principles on which to base local standards.[15]

A proposal for joint action

What distinguishes the GPP standards from any guideline provided by a professional association is that they are legally binding. This would also allow for the GPP standards to be relied upon by the OHSC when accrediting health facilities, as required for NHI. However, what is needed is far more clarity than is provided by circular references to Regulation 36. The following provides a short indicative list of some of the areas where clarity is currently lacking, and where detailed practice standards would be of great assistance to pharmacists:

- Control of medicines, including specified Schedule 5 and Schedule 6 substances, in emergency departments, operating theatres, day clinics and wards.
- Control over emergency after-hours medicine stocks.
- Handling telephonic orders from prescribers to nursing staff on wards.
- Handling "standing orders" in hospitals.
- Supply of medication to in-patients being discharged after pharmacy operating hours.
- Preparation of cancer chemotherapy products in wards and consulting rooms within hospitals.
- Appropriate control over parenteral nutrition products, including clarity on the relative roles of pharmacists, dieticians and attending medical staff.

This list focuses on the needs of hospital pharmacy, but there are also challenges with the provision of pharmaceutical services in primary care facilities, notably with psychiatric services.

SAAHIP has a proud history of contributing to the development of the accreditation standards that were previously developed by the Council for Health Service Accreditation of Southern Africa (COHSASA). It is recommended that SAAHIP convene a consultation process to identify topics that require amendment in the GPP, and then jointly develop practical, enforceable and appropriate amendments to the current standards, together with the SAPC and its Practice Committee. To do so will not only contribute to patient safety and well-being, but also address the needs of hospital pharmacists who are currently struggling to deliver a safe, effective and comprehensive pharmaceutical service under conditions of uncertainty and with severely constrained human and other resources.

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Are we stuck in the old way of practising pharmacy?

Joggie Hattingh, President: SAAHIP

Joggie Hattingh

I have recently started wondering if our profession is as effective as we think we are!

We have submitted wonderful documents to government on pricing structures, NHI and quite a number of other issues, but we do not get the reaction we thought appropriate to these well drafted and crafted documents. Then I took a step back and thought about the number of huge documents and legislation that has been coming across my desk on a weekly basis the past few years.

Do I read them in detail? It is so laborious and time consuming that instead of reading it weekly, I do so very weakly! No one has the time to go through all these documents in detail, unless it is your job to do so! Most of us look for the essence of the document and if it is not craftily summarised early in the document we place a marker against it and with the best of intentions to revisit it later, shift it to Neverland!

In our practice, we have been doing things in a pertinent way for years and our pharmacies are organised in a specific order for as long as we remember. We treat our patients and members of the multi-disciplinary team in the exact manner as we have for all these years! How can there be anything wrong with it?

It is sometimes necessary to take a step back and evaluate ourselves from a distance and just maybe if we do, we may find that we have spun ourselves into a cosy cocoon! If it is the case, it is now time to complete the metamorphosis. Like an egg, a cocoon can be broken in two ways. If we allow someone to do it from the outside it means the death of the organism, but if it is broken from the inside, a wonderful new life will emerge! The choice is ours!

And the best of all is that the organism emerging from the cocoon or egg is not unrelated to what it was, it is actually even better! We truly do not need to lose any of the core values we hold dear.

Electronic media does give us good options for communication, but it should not and cannot replace good interpersonal relationships! Only when a good relationship exists with members of the multi-disciplinary team, do electronic media become useful. So we need to get out of our pharmacies and out from behind our desks and we need to interact with all members of our team, if we want attitudes to change.

We need to be brave enough to start tearing at the confines of the cocoon or egg shell, and YES – it will be painful. There is of course the other option…