Prescribing in South Africa: what's next?

Andy Gray
Division of Pharmacology
Discipline of Pharmaceutical Sciences
Outline

- Why extend prescribing rights beyond the usual list of authorised prescribers?
- Is NIMART the only option? What about other (potential) prescribers or other conditions?
- The legal provisions in South Africa – an enabling environment; the first steps; the next steps
A. Recommendations on adopting task shifting as a public health initiative

• Every health system faces HRH constraints
• Task-shifting is about efficiency and effectiveness, not merely an emergency option when all others have been exhausted
Is there scope for cost savings and efficiency gains in HIV services?
A systematic review of the evidence from low- and middle-income countries

Mariana Siapka, Michelle Remme, Carol Dayo Obure, Claudia B Maier, Karl L Dehne & Anna Vassall

**Objective** To synthesize the data available – on costs, efficiency and economies of scale and scope – for the six basic programmes of the UNAIDS Strategic Investment Framework, to inform those planning the scale-up of human immunodeficiency virus (HIV) services in low- and middle-income countries.

**Methods** The relevant peer-reviewed and “grey” literature from low- and middle-income countries was systematically reviewed. Search and analysis followed Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines.

**Findings** Of the 82 empirical costing and efficiency studies identified, nine provided data on economies of scale. Scale explained much of the variation in the costs of several HIV services, particularly those of targeted HIV prevention for key populations and HIV testing and treatment. There is some evidence of economies of scope from integrating HIV counselling and testing services with several other services. Cost efficiency may also be improved by reducing input prices, task shifting and improving client adherence.

**Conclusion** HIV programmes need to optimize the scale of service provision to achieve efficiency. Interventions that may enhance the potential for economies of scale include intensifying demand-creation activities, reducing the costs for service users, expanding existing programmes rather than creating new structures, and reducing attrition of existing service users. Models for integrated service delivery – which is, potentially, more efficient than the implementation of stand-alone services – should be investigated further. Further experimental evidence is required to understand how to best achieve efficiency gains in HIV programmes and assess the cost-effectiveness of each service-delivery model.

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The impact of HIV/SRH service integration on workload: analysis from the Integra Initiative in two African settings

Sedona Sweeney1,2, Carol Dayo Obure1, Fern Terriis-Prestholt1, Vanessa Dasamo1, Christine Michal's Igbokie1, Esther Muku10, Zeli Nhabutu10, Charlotte Warren1, Susannah Mayhew1, Charlotte Watts1, Anna Vassall1 and the Integra Research Team

Integration

- Increased availability of services
- Consolidation of human resources
- Consolidation of physical resources

- Increased output
- Reduced staff time / increased workload
- More efficient allocation of staff duties
- More efficient allocation of physical space

- Economies of Scale
- Economies of Scope

Context

- Facility characteristics, staff knowledge / training, management support, equipment / supply availability
- National & international policy environment / health systems infrastructure
- Population characteristics & risk behaviours / demand for integration

Figure 1 Economic impact of integration.
“….NIMART is widely practiced and authorized in policy, but is not reinforced by regulation nor incorporated into pre-service education. Further investment in policy, regulation, and pre-service education is needed to ensure sustainable, high quality ART service expansion through the region.”
<table>
<thead>
<tr>
<th>Country</th>
<th>Specialized Populations</th>
<th>Nurse Cadres that Initiate and Manage ART</th>
<th>Years of Post-basic Education Required for these Cadres</th>
<th>ART Sites Where NIMART is Occurring</th>
<th>Type of Health Facilities Where NIMART is Practiced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>No</td>
<td>Registered nurse, nurse specialist (nurse midwife, family nurse practitioner)</td>
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<td>Primary care, TB/HIV, PMTCT</td>
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<tr>
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</tbody>
</table>

Note: NIMART = Nurse Initiated and Managed Antiretroviral Therapy; ART = antiretroviral therapy; PMTCT = prevention of mother-to-child transmission; TB = tuberculosis.
<table>
<thead>
<tr>
<th>Country</th>
<th>Document that Formally Authorizes NIMART</th>
<th>The Nursing Scope of Practice Allows Nurses to Prescribe &amp; Manage ART</th>
<th>NIMART is Recognized Form of Nursing Specialization</th>
<th>NIMART Content is Included in the National Credentialing Examination for Nurses</th>
<th>NIMART Training is Accredited or Approved by National Nursing Council</th>
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<td>Swaziland</td>
<td>Scope of Practice, ART Guidelines</td>
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<td>No exam exists</td>
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<td>Uganda</td>
<td>The strategic and investment plan for health 2010–2015: HIV manpower policy</td>
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*Note: NIMART = Nurse-Initiated and -Managed Antiretroviral Therapy; ART = antiretroviral therapy; MOH = Ministry of Health; n/a = respondents did not provide an answer to the question; unsure = respondents were unsure or could not reach consensus.*
Outcomes of a nurse-managed service for stable HIV-positive patients in a large South African public sector antiretroviral therapy programme

Anna Grimsrud¹, Richard Kaplan², Linda-Gail Bekker²,³ and Landon Myer¹,²

1 Division of Epidemiology & Biostatistics, School of Public Health & Family Medicine, University of Cape Town, Cape Town, South Africa
2 Desmond Tutu HIV Centre, Institute of Infectious Disease and Molecular Medicine, University of Cape Town, Cape Town, South Africa
3 Department of Medicine, University of Cape Town, Cape Town, South Africa

Abstract

OBJECTIVES Models of care utilizing task shifting and decentralization are needed to support growing ART programmes. We compared patient outcomes between a doctor-managed clinic and a nurse-managed down-referral site in Cape Town, South Africa.

METHODS Analysis included all adults who initiated ART between 2002 and 2011 within a large public sector ART service. Stable patients were eligible for down-referral. Outcomes [mortality, loss to follow-up (LTFU), virologic failure] were compared under different models of care using proportional hazards models with time-dependent covariates.

RESULTS Five thousand seven hundred and forty-six patients initiated ART and over 5 years 41% (n = 2341) were down-referred; the median time on ART before down-referral was 1.6 years (interquartile range, 0.9–2.6). The nurse-managed down-referral site reported lower crude rates of mortality, LTFU and virologic failure compared with the doctor-managed clinic. After adjustment, there was no difference in the risk of mortality or virologic failure by model of care. However, patients who were down-referred were more likely to be LTFU than those retained at the doctor-managed site (adjusted hazard ratio, 1.36; 95% CI, 1.09–1.69). Increased levels of LTFU in the nurse-managed vs. doctor-managed service were observed in subgroups of male patients, those with advanced disease at initiation and those who started ART in the early years of the programme.

CONCLUSION Reorganization of ART maintenance by down-referral to nurse-managed services is associated with programme outcomes similar to those achieved using doctor-driven primary care services. Further research is necessary to identify optimal models of care to support long-term retention of patients on ART in resource-limited settings.
Task shifting from doctors to non-doctors for initiation and maintenance of antiretroviral therapy (Review)

Kredo T, Adeniyi FB, Bateganya M, Plenaar ED

<table>
<thead>
<tr>
<th>Baseline CD4 count (All studies)</th>
<th>Other baseline variables (All studies)</th>
<th>Co-interventions (All studies)</th>
<th>Random sequence generation (Trials)</th>
<th>Allocation concealment (Trials)</th>
<th>Contamination Protection (Trials)</th>
<th>Data collection (Cohorts)</th>
<th>Patient selection bias (Cohorts)</th>
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Figure 5. Forest plot of comparison: 2 Doctor versus nurse or clinical officer (Maintenance of ART), outcome: 2.1 Death (12 months).

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Task-shifting Events</th>
<th>Doctor care Events</th>
<th>Risk Ratio M.H., Random, 95% CI</th>
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<tbody>
<tr>
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<tr>
<td>2.1.1 Maintenance of ART (RCTs)</td>
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</tr>
<tr>
<td>Fairall 2012 (1)</td>
<td>37</td>
<td>1711</td>
<td>0.93 [0.60, 1.44]</td>
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<tr>
<td>Sarne 2010</td>
<td>5</td>
<td>404</td>
<td>0.67 [0.24, 1.97]</td>
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<td>Subtotal (95% CI)</td>
<td>2115</td>
<td>2217</td>
<td>0.89 [0.59, 1.32]</td>
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<tr>
<td>Total events</td>
<td>40</td>
<td>51</td>
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<td>Heterogeneity: Tau² = 0.00; Ch² = 0.23, df = 1 (P = 0.57); P = 0%</td>
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<td>Test for overall effect: Z = 0.59 (P = 0.56)</td>
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2.1.2 Maintenance of ART (Cohorts)

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<th>Study or Subgroup</th>
<th>Task-shifting Events</th>
<th>Doctor care Events</th>
<th>Risk Ratio M.H., Random, 95% CI</th>
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</thead>
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<td>603</td>
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<tr>
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<td>Total events</td>
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(1) Average cluster size 155, ICC = 0.005, design effect = 1.77

Figure 6. Forest plot of comparison: 2 Doctor versus nurse or clinical officer (Maintenance of ART), outcome: 2.2 Lost to follow-up (12 months).

<table>
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<tr>
<th>Study or Subgroup</th>
<th>Task-shifting Events</th>
<th>Doctor care Events</th>
<th>Risk Ratio M.H., Random, 95% CI</th>
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<tr>
<td>2.2.1 Maintenance of ART (RCTs)</td>
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2.2.2 Maintenance of ART (Cohorts)

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<td>Subtotal (95% CI)</td>
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<td>2079</td>
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(1) Average cluster size 155, ICC = 0.005, design effect = 1.77
What about other prescribers and other conditions?

“…. task-shifting is a viable and successful model and is potentially cost-effective and clinically effective for the management of NCDs. For a task-shifting model of care to function optimally several changes need to be made at the health policy and health systems level including scaling up training programs for NPHWs, provision of standardized protocols, adequate equipment and drug supply, integration of NPHWs as part of a multi-disciplinary team with support from physicians, and consultation with regulatory bodies such as the medical and nursing councils. With such systems supports in place there are substantial opportunities for major improvements in healthcare quality and outcomes for NCD management in LMICs.”
Acceptability and feasibility of using non-specialist health workers to deliver mental health care: Stakeholder perceptions from the PRIME district sites in Ethiopia, India, Nepal, South Africa, and Uganda

Emily Mendenhall a, b, *, Mary J. De Silva a, Charlotte Hanlon c, d, Inge Petersen e, Rahul Shidhaye f, Mark Jordans c, g, Nagendra Luitel h, Joshua Ssebunya i, Abebaw Fekadu d, j, Vikram Patel a, f, k, Mark Tomlinson l, m, Crick Lund l

a Center for Global Mental Health, London School of Hygiene and Tropical Medicine, London, United Kingdom
b School of Foreign Service, Georgetown University, Washington, DC, United States
c Center for Global Mental Health, Institute of Psychiatry, King’s College London, London, United Kingdom
d Addis Ababa University, College of Health Sciences, School of Medicine, Department of Psychiatry, Addis Ababa, Ethiopia
e University of KwaZulu-Natal, Durban, South Africa
f Centre for Mental Health, Public Health Foundation of India, New Delhi, India
g HealthNet TPO, Amsterdam, The Netherlands
h TPO Nepal, Kathmandu, Nepal
i Makerere University, Kampala, Uganda
j King’s College London, Institute of Psychiatry, Department of Psychological Medicine, the Affective Disorders Research Group, London, United Kingdom
k Sangath, Goa, India
l Alan J Fisher Centre for Public Mental Health, Department of Psychiatry and Mental Health, University of Cape Town, Cape Town, South Africa
m Stellenbosch University, Stellenbosch, South Africa
But, a timely warning ....

“Not clearly defining what needs to be performed by which health cadres has become a major barrier for determining what training and supervision should be provided, especially among community and PHC workers who already are overburdened with tasks.”
An enabling environment – National Drug Policy, 1996

“Prescribing of drugs above schedule 2 by pharmacists, except as provided in the regulations of the Medicines and Related Substances Control Act (101 of 1965), will not be permitted. Similarly, prescribing by nurses will only be in accordance with the provisions of Act 101 of 1965.

The objective is to ensure that all health personnel involved in diagnosis, prescribing and dispensing of drugs receive adequate theoretical and practical training.

At primary level prescribing will be competency, not occupation, based.

Only practitioners who are registered with the relevant Council and premises that are registered and/or licensed in terms of the Medicines and Related Substances Control Act (No 101 of 1965) may be used for the manufacture, supply and dispensing of drugs.”
Enabling a range of prescribers – Medicines Act

- Section 22A(5) of the Medicines and Related Substances Act (Act 101 of 1965):
  Any Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance shall not be sold by any person other than:
  a) a pharmacist, pharmacist intern or a pharmacist's assistant acting under the personal supervision of a pharmacist, who may sell only Schedule 2 substances without a prescription;
  b) a pharmacist or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription issued by an authorised prescriber or on the verbal instructions of an authorised prescriber who is known to such pharmacist;
  c) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;
  d) a medical practitioner or dentist, who may:
     i. prescribe such substance;
     ii. compound or dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);
  e) a veterinarian who may prescribe, compound or dispense such substance;
  f) a practitioner, a nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may:
     i. prescribe only the Scheduled substances identified in the Schedule for that purpose;
     ii. compound and dispense the Scheduled substances referred to in subparagraph (i) only if he or she is the holder of a licence contemplated in section 22C (1) (a).
SCHEDULE 1

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –
   (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and
   (ii) analytical laboratory purposes.

b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:
   (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and
   (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

c. In terms of section 22A(4)(a)(v) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 1 substances and medicines provided for in the Annexures to this Schedule published in the Gazette in terms of the Act.

   (i) Annexure 1A: Emergency Care Provider (Paramedic);
   (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
   (iii) Annexure 2: Dental Therapist;
   (iv) Annexure 3: Optometrist.
A critical step ....

- s22A(14) Notwithstanding anything to the contrary contained in this section-
  
a) …
  
b) no nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe a medicine or Scheduled substance unless he or she has been authorised to do so by his or her professional Council concerned.
Nursing Act (Act 33 of 2005) - promulgated in its entirety

56. (1) Despite the provisions of this Act or any other law, the Council may register a person who is registered in terms of section 31(1)(a), (b) or (c) to assess, diagnose, prescribe treatment, keep and supply medication for prescribed illnesses and health related conditions, if such person-

(a) provides proof of completion of prescribed qualification and training;
(b) pays the prescribed registration fee; and
(c) complies with subsection 6.

(2) The Council must issue a registration certificate to a person who complies with the requirements referred to in subsection (1).

(3) The registration certificate referred to in subsection (2) is valid for a period of three years.

(4) The Council may renew a registration certificate referred to in subsection (2) subject to such conditions as the Council may determine.

(5) A person registered in terms of subsection (1) may -

(a) acquire, use, possess or supply medicine subject to the provisions of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965); and
(b) dispense medicines subject to the provisions of the Medicines and Related Substances Act, 1965.
S56(6) - a retro-fit of s38A

(6) Despite the provisions of this Act, the said Medicines and Related Substances Act, 1965, the Pharmacy Act, 1974 (Act No. 53 of 1974), and the Health Professions Act, 1974 (Act No. 56 of 1974), a nurse who is in the service of-

(a) the national department;
(b) a provincial department of health;
(c) a municipality; or
(d) an organisation performing any health service designated by the Director-General after consultation with the South African Pharmacy Council referred to in section 2 of the Pharmacy Act, 1974, and who has been authorised by the Director-General, the head of such provincial department of health, the medical officer of health of such municipality or the medical practitioner in charge of such organisation, as the case may be, may in the course of such service perform with reference to-

(i) the physical examination of any person;
(ii) the diagnosing of any physical defect, illness or deficiency in any person; or
(iii) the keeping of prescribed medicines and their supply, administering or prescribing on the prescribed conditions;

any act which the said Director-General, head of provincial department of health, medical officer of health or medical practitioner, as the case may be, may, after consultation with the Council, determine in general or in a particular case or in cases of a particular nature, if the services of a medical practitioner or pharmacist, as the circumstances may require, are not available.

(7) A person contemplated in subsection (1) is not entitled to keep an open shop or pharmacy.

(8) For the purpose of subsection (7) “open shop” means a situation where the supply of medicines and scheduled substances to the public is not done by prescription by a person authorised within the scope of practice concerned to prescribe medicine.
http://sahivsoc.org/

Prescribing and dispensing by nurses
neglected steps in the legislative process

While there is wide acceptance of nurse-initiation and management of antiretroviral therapy (NIM-Art), the legal means to enable nurses to be recognised as authorised prescribers remain elusive. Section 56(1) to (5) of the Nursing Act (Act 33 of 2005) enables nurses to be issued with a permit to keep, prescribe and supply medicines in the absence of a medical practitioner or pharmacist. However, this should be seen as a temporary or transitional mechanism, and not as a long term solution. Sections 56(1) to (5) need to be brought into effect so that nurses can be recognised as authorised prescribers and so that patients can have access to the full set of services, including a full pharmaceutical service. Only by basing access to prescribing (and dispensing) on demonstrated competence can a safe and effective system of task-shifting be put into effect.

Andy Gray
Senior Lecturer
Department of Therapeutics and Medicines Management
Nelson R Mandela School of Medicine
University of KwaZulu-Natal
email: graya1@ukzn.ac.za
or andygrayza.net
GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 1044 14 December 2011

SOUTH AFRICAN NURSING COUNCIL
NURSING ACT, 2005 (ACT NO. 33 OF 2005)

REGULATIONS RELATING TO THE KEEPING, SUPPLY, ADMINISTERING, PRESCRIBING OR DISPENSING OF MEDICINE BY REGISTERED NURSES

The Minister of Health intends to, after consultation with the South African Nursing Council, in terms of section 58(1)(a) read with section 58 of the Nursing Act, 2005 (Act No. 33 of 2005), make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations in writing on the proposed regulations to the Director-General: Health, Private Bag X628, Pretoria, 0001 (for attention of the Director: Public Entities and Management) within three months from date of publication of this notice.
THE SOUTH AFRICAN PHARMACY COUNCIL

SCOPE OF PRACTICE AND QUALIFICATION FOR AUTHORISED PHARMACIST PRESCRIBER

The South African Pharmacy Council (the Council) intends to request the Minister of Health to:
(a) publish amendments to the Regulations relating to the registration of persons and the maintenance of registers to make provision for a new category of pharmacist namely the authorised pharmacist prescriber;
(b) publish amendments to the Regulations relating to the practice of pharmacy to make provision for the scope of practice of the authorised pharmacist prescriber; and
(c) publish regulations in terms of Sections 33 and 49(mA) to provide the required qualifications for the authorised pharmacist prescriber.

The qualification and the proposed scope of practice are published herewith for public comment prior to the said request/s to the Minister of Health.

SCHEDULE

1. Scope of practice of Authorised Pharmacist Prescriber

2. Qualification for Authorised Pharmacist Prescriber

In this notice “the Act” shall mean the Pharmacy Act 53 of 1974, as amended, and any expression to which a meaning has been assigned in the Act shall bear such meaning.

Interested persons are invited to submit, within 30 days of publication of this notice, substantiated comments or representations on the qualification and scope of practice to the Registrar, The South African Pharmacy Council, Private Bag X40040, Arcadia, 0007, or Fax 086 5063010 or email: debbie.hofmann@sapc.za.org (for the attention of the Senior Manager: Legal Services and Professional Conduct).

TA MASANGO
REGISTRAR
Regulations - Government Notice
No. R. 24182 November 1984

Regulations relating to the keeping, supply, administering or prescribing of medicines by Registered Nurses

In terms of section 45 of the Nursing Act, 1978 (Act 50 of 1978), the Minister of Health and Welfare, acting on the recommendation of the South African Nursing Council, has made the regulations set out in the Schedule hereto.

SCHEDULE

1. In the Schedule "the Act" shall mean the Nursing Act, 1978 (Act 50 of 1978), and any expression to which a meaning has been assigned in the Act shall bear such meaning and, unless the context otherwise indicates:

"authorised nurse" shall mean a registered nurse mentioned in section 38A of the Act [Note (1)];
"Medicines Control Act" shall mean the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965);
"prescribed medicine" shall mean a medicine or related substance mentioned in regulation 2;
"re-packed form" shall mean packaging of prescribed medicine prepacked from bulk for the immediate use of a patient;
"section" shall mean a section of the Act;
"unscheduled medicine" shall mean any medicine or related substance not listed in any Schedule to the Medicines Control Act.

2. An authorised nurse may, subject to the provisions of section 38A and the conditions listed in regulation 3, keep the following and supply, administer or prescribe it for the use of a person:

(a) An unscheduled medicine;
(b) any medicine or substance listed in Schedule 1, Schedule 2, Schedule 3 or Schedule 4 to the Medicines Control Act.
Evidence of progress - slowly

South African Nursing Council - Professional Practice for Nurses and Midwives

Competencies for Advanced Practice Nurses

COMPETENCY DOCUMENTS

The South African Nursing Council has developed the following competencies for Advanced Practice Nurses:

- Generic Competency Framework for Advanced Nurse Practitioners
- Competencies - Critical Nurse Specialist (Adult)
- Competencies - Forensic Nurse
- Competencies - Midwife Specialist
- Competencies - Nephrology Nurse Specialist
- Competencies - Occupational Health Nurse Specialist
- Competencies - Ophthalmic Nurse Specialist
- Competencies - Orthopaedic Nurse Specialist
- Competencies - Paediatric Nurse Specialist
- Competencies - Primary Care Nurse Specialist

ADDITIONAL INFORMATION

For information on the relationships between Scopes of Practice, Practice Standards and Competencies, see the following document.
In conclusion

- The enabling environment exists, in policy (though dated) and in law (though neglected)
- The next steps need to be taken by the individual professional councils, to propose listings in the Schedules by the Minister (on the advice of the MCC)
- However, this needs to be within a co-ordinated HRH strategy of task-shifting and collaborative practice (using both dependent and independent prescriber options)