PathCare

Drs Dietrich, Voigt, Mia

Vennote Partners

Written Submission on the Policy Paper: National Health Insurance in South Africa

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22 December 2011

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Ms Matsoso
Director-General: National Department of Health
Civitas Building
Cnr Andries and Struben Streets
PRETORIA

Dear Madam

PATHCARE SUBMISSION IN RESPONSE TO THE POLICY PAPER: NATIONAL HEALTH INSURANCE IN SOUTH AFRICA

Please find enclosed comments on the released NHI Greenpaper from PathCare (Drs Dietrich, Voigt, Mia and Partners), a pathology practice with laboratories operating in South Africa and Namibia.

We hope our input and feedback to be of use and constructive.

Yours sincerely,

JW Douglass

John Douglass
CEO PathCare

Written submission by Drs Dietrich Voigt Mia and Partners ("PathCare") on the Policy Paper: National Health Insurance in South Africa

INTRODUCTION

In the Government Gazette No 34523 dated 12 August 2011, the Minister of Health ("the Minister") invited public comment on the National Health Act Policy on National Health Insurance.

PathCare thanks the Minister for the opportunity to comment through this written submission.

We kindly request an opportunity to engage in consultative meetings with the Ministry and Department of Health as part of the laboratory medicine establishment.

We also declare our wish to participate in the pilot implementation of NHI. Our presence in the Mangaung District, Free State which is ear-marked for piloting, could assist in blueprinting the co-operation (and support) of the private sector to the NHI. **PathCare** is a significant South African healthcare entity that employs over 2500 people and provides laboratory services to over 3.2 million South Africans per year. Further details regarding **PathCare** can be found in ***Annexure A***.

EXECUTIVE SUMMARY

PathCare supports the establishment of a national health insurance (NHI) framework. Improving access to quality healthcare is a national priority.

The NHI policy document lists seven key principles which must be addressed:

- The right to access
- Social solidarity
- Effectiveness
- Appropriateness
- Equity
- Affordability
- Efficiency

The **right to access**, established as "the right of access to healthcare" in the Bill of Rights and the South African Constitution, can best be achieved by **leveraging off all the resources** we currently have at our disposal, both public and private. We believe medical laboratories have capacity to provide excellent access to pathology services. **PathCare** alone provides access to laboratory services to **3.2 million patients in SA per annum** (**28% of these are in Primary Care** and 27% are in rural areas). We propose that to achieve improved access in primary healthcare, a key consideration for the NHI is **to incorporate phlebotomy technicians into the clinical team** at district level to assist in basic diagnostics and quality assurance practices. See ***Annexure B.***

To ensure **social solidarity**, we agree that healthcare must be available to all the citizens of South Africa, based on ethically acceptable Principles, including distributive justice. All South Africans must therefore participate and contribute to the funding of NHI, with an understanding that contributions are an investment in the good health of our society, through cross-subsidisation on the basis of this solidarity between the young and the old, the healthy and the sick, rich and poor, and between those paying more and those paying less (or nothing). **PathCare** suggests that, for solidarity to be workable, actuarial assessments and

clarity on the practical implications of concepts such as risk-equalisation and risk-adjusted payments (as mooted in the Green Paper) will be essential.

To ensure **equity**, our NHI system must ensure that the needs of vulnerable groups (women, children, unemployed and disabled) are catered for and that barriers to access are removed. This will best be **achieved by leveraging off all resources at our disposal, both private and public,** as seen in ***Annexure B.***

To ensure **effectiveness**, the NHI framework must focus on disease prevention, disease screening, early detection and effective disease management, through the prudent application of **Evidence-based Medicine** (*"the conscientious, explicit and judicious use of current best evidence in making decisions about the care of beneficiaries whereby individual clinical experience is integrated with the best available external clinical evidence from systematic research"*). Laboratory Medicine has a critical role to play in this, as shown in International research. See ***Annexure C***.

Furthermore, ensuring effectiveness and delivery of a quality healthcare service requires that controls must be in place to ensure that the **quality of service is never compromised and services are effectively used. No other discipline in healthcare provision has a better track-record than Laboratory Medicine** in consistently measuring and monitoring quality. **PathCare**, and indeed Laboratory Medicine overall, has significant experience in the setting of minimum expected standards, audit of practice against such standards, the ability to reduce or eliminate error, meeting customer expectations, with consequent successful achievement of accreditation requirements, and sustainable attainment of quality objectives. In ***Annexure D***, we attach a summary of the history of quality assurance processes in our organisation and share our thoughts on how the NHI framework and the Office of Health Standards Compliance (OHSC) could benefit from internationally accepted quality assurance. We recommend that, insofar as laboratory medicine is concerned, standards are aligned and that accreditation, and enforcement of the standards is harmonised between, for example, the system envisaged by the proposed medical device licensing regulation, the control of Hazardous Substances system and ISO accreditation, as well as the licensing system referred to in the *HRH Strategy*, 2011. **PathCare** further proposes that bodies looking into setting effective and appropriate clinical care guidelines should comprise representatives of all affected disciplines.

Congruence and alignment with the EDL, EEL and Essential Pathology Lists is important. To ensure consistent application of the provider-buyer split, **PathCare** contends that specific buying and budget-impact decisions should be separate from clinical guideline setting functions, as these may be determined by factors such as population size, disease prevalence, co-morbidities, outcomes, etc.

To ensure **appropriateness**, (viz. that the patient must get the right treatment at right time for right condition at right place), Primary Healthcare services must be strengthened in the NHI system. Primary healthcare workers must be empowered to effectively provide care, including being able to interact with, and undertake diagnostics, where necessary. **Appropriate use of pathology early on in diagnostic algorithm has been shown to lessen down-stream costs resulting from complications of poor management**. In ***Annexure E***, we share our thoughts on how pathology can be used to ensure appropriateness. Appropriateness is a function of clinical governance. **PathCare** proposes that laboratory diagnostics (including Point-of-Care diagnostics) form part of the national standard treatment guidelines (currently available in the so-called EDL books – primary, hospital and paediatric care).

To ensure **affordability** of healthcare delivery to the nation, the **judicious use of pathology testing contributes to early and correct diagnosis** ("70% of clinical decisions are informed by laboratory medicine", NHS), **management and monitoring of disease**. For example, the diagnosis, staging, management and monitoring of **HIV epidemic** ensures that the epidemic is controlled, deaths are prevented, life expectancy is extended, and economically active individuals potentially return to productivity. Similarly, cost efficient cancer treatment will never be as effective in ensuring affordability compared to prevention and screening – for example **cervical cancer**. ***Annexure F*** contains extracts from published research.

To ensure **efficiency**, the NHI framework must foster competition. **Patient choice ensures providers deliver efficiently**. Competition is critical to ensuring effective access, as it decreases inequalities, waiting times, waiting lists and increases availability. The NHS in the UK has acknowledged the need for competition, and has demonstrated numerous examples where patient choice enhanced outcomes (both patient reported outcomes and clinical outcomes) In ***Annexure G*** we table a detailed overview highlighting the importance of choice within NHI. A summary of the need for competition is attached as ***Annexure H***.

The greatest challenges in implementing NHI are ensuring that the necessary human resources are in place and that the system we build is sustainable.

To ensure our NHI framework has the **human resources** it needs, we need to ensure that healthcare workers feel valued, are effectively remunerated, have the freedom to practice professionally within an appropriate regulatory framework, can choose where they work and are empowered to improve the health of all South Africans. Ensuring sufficient supply of healthcare practitioners is a recognised health sector priority and we relate our proposals in this regard to the recently released *HRH Strategy*. This is critical to he success of NHI. We are confident that the department will engage the necessary expertise to ensure that South African healthcare workers want to work in South Africa. **PathCare has contributed significantly to HR skills development** and has the capacity to enhance this even further – see ***Annexure I.***

To ensure **financial sustainability**, the South African healthcare system needs appropriate financing, and efficient service delivery through appropriate care and elimination of waste. Pricing and reimbursement mechanisms must take into account the realities of costs incurred, service to be delivered and sustainability over the long term. We provide more details in how health services should be reimbursed to ensure fairness towards providers, as well as sustainability in the system in ***Annexure J***.

We trust that you will find our submission informative and the thoughts we share valuable in developing a NHI framework that delivers on the key principles within the policy document.

Whilst we have focused on key issues in this submission, not all issues have been addressed comprehensively, and **PathCare** reserves its rights to comment on issues not raised in this submission, or issues that may emerge in the publication of the White Paper or as the process unfolds.

We look forward to working towards NHI and would welcome questions and further engagements regarding this submission.

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ANNEXURES

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ANNEXURE A

PathCare Organisational Overview

- **PathCare** (Drs Dietrich Voigt Mia and Partners) is a partnership of pathologists and technologists that provides medical laboratory investigations (predominantly blood tests) for doctors and other healthcare workers in South Africa and Namibia.
- **PathCare** has over 150 referral sites where patients can be attended to by qualified phlebotomists and nursing staff. Sixty three of these sites include a laboratory either in hospital or near hospital to be able to provide results as rapidly as possible.
- We have 80 pathologists in all disciplines of pathology and over 2,500 staff including nursing staff, medical technologists, technicians, phlebotomists, laboratory assistants, couriers, etc.
- **PathCare** covers the Western Cape, Northern Cape, North West, Free State Eastern Cape, and Gauteng in South Africa.
- **PathCare** collects specimens from hospitals and doctors' rooms including outlying areas and smaller towns in all these provinces.
- We are a proudly South African business with operations in Nigeria, Kenya, Lesotho, and Namibia.
- **PathCare** was the first South African medical laboratory to receive accreditation through the South African National Accreditation System (SANAS).
- Specimens are analysed in laboratories that adhere to ISO guidelines and the results are communicated to doctors by multiple means, including post, and electronically through a **PathCare** secure internet system.
- Through the healthcare worker, **PathCare** provides the most valuable investigative service that ultimately benefits the patient.
- **PathCare** has developed strong relationships with allied professionals, including the National Health Laboratory Service, and continues to be committed to working with other service providers to improve delivery and accessibility in a cost effective way.
- Private medical schemes consider **PathCare** to be the most cost effective pathology laboratory in the country.
- **PathCare** is committed to skills development and its laboratories are accredited training institutions. Over the past 5 years, the **PathCare** Training Academy has trained 84 Medical Technologists, 148 Medical Technicians, 93 Phlebotomy Technicians, and 92 Laboratory Assistants. This represents 9% of Medical Technologists; 13% of Medical Technicians; 30% of Phlebotomy Technicians; and 42% of Laboratory Assistants in South Africa. Short courses specific to the needs of employees are presented regularly, with over 17,000 courses presented over the past 5 years (thus every member of staff has had access to an average of 1.5 short courses per annum.)

QualiCare

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Dear Dr Douglass, **15/12/2011**

I have read your submission on NHI and would like you to include, if possibly, comments from CPC/Qualicare regarding GP Pathology. As you are aware, CPC/Qualicare is the largest independently GP run IPA in the Western Cape with over 600 GP members.

The right of access to healthcare by SA Citizens is underpinned in our close cooperation and alignment with PathCare.
Our GPs are concentrating on the formation of group practices, in which there will be the possibility of venisection points of care in the larger groups, done by trained venisectionist or by the doctors themselves thereby offering a potential of over 300 further points of service for patients using the services of PathCare.

Many of our GPs service patients on managed care options, as well as concentrate on the previously disadvantaged population who do not enjoy easy access to private healthcare. This is often done by way of a “package deal”. We thank PathCare for their sensitivity to requests from the GP population to assist, where warranted, with offering day to day pathology at a discounted rate for these persons. Thus our and PathCare’s commitment to social solidarity is reflected in the aforegoing and is both complimentary and congruent.

CPC/Qualicare noted PathCare’s commitment to appropriateness and affordability in pathology testing by minimising batch testing, and for their contribution to the Unitary Pathology GP request form.

Once again your commitment to social solidarity and equity shines through in your support of our unitary request form project.

Finally, it would be incomplete for me not to comment on your speed of processing results, and the accuracy thereof. Your turnaround time sets the bar for the rest of the pathology industry and your accuracy is a source of comfort to the GPs using your services.

Thank you for your ongoing commitment to GP pathology in the Western Cape.

Yours sincerely,
Dr A D Behrman
CEO CPC/Qualicare

CPC DOCTOR’S FUND (PTY) LTD T/A QUALICARE
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SAMCC
Proud co-founder member of the
SA Managed Care Cooperative

ANNEXURE B

Access to Services and Equity for NHI

The best way to ensure equitable distribution of healthcare services is to optimally use all the currently available resources, and to increase the sources of supply. The absence of (certain or all) pathology services in some areas, inaccurate results and delayed results all have a detrimental impact on access to healthcare. **Pathcare** supports all initiatives that strive to increase the number of pathologists, associated professionals and pathology providers as these ultimately contribute towards improved access, efficiency
and affordability.

3.2 Million patients per annum receive services from PathCare. We perform just under **12 Million tests per annum**, through 115 laboratories and blood collection depots, **27% of which are in rural areas**, such as Kuruman and Kathu in Northern Cape, Queenstown in Eastern Cape, Harrismith in Free State and Mafikeng in North-West Province. Our couriers travel over 8 million km annually collecting specimens from very remote areas such as Prince Albert, Kwa-Kwa and Leeudoring stad. **28% of tests are requested by Primary Care Practitioners.**

Access to basic diagnostic services can be further extended through the incorporation of **phlebotomy technicians into the clinical team** at district level to assist in appropriate specimen taking, basic diagnostics through Point-of-Care (or near patient) testing and the requisite quality assurance practices to ensure a valid and reliable result.

ANNEXURE C

The Role of Pathology Services and Diagnostics in Ensuring Effectiveness in NHI

Pathology services help to reduce the progression of illness and disease. Screening for risk factors (e.g. cholesterol), early detection of disease (e.g. HIV, TB), the identification of other infectious diseases and appropriate therapy (e.g. for MDR TB) and, the monitoring of patients' clinical progress (e.g. in hospital ICU) is enabled by pathology services.

The following extracts from an article published by the Lewin Group (Inc) in September 2009 entitled **"The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement"** provide the evidence for and demonstrate the importance of the role of Pathology and Laboratory Medicine (bold = our emphasis):

"Health care system stakeholders (including payers, providers, patients, accreditation and quality improvement organizations, health services researchers, policymakers, industry) agree that ***increasing value to patients can be achieved*** *by improving quality through the types of goals shown in Box 1.* ***Laboratory screening and diagnostic tests are essential for pursuing many of these goals****."*

BOX 1: Health System Goals for Increasing Quality and Value

- Prevention
- Early detection
- Right diagnosis
- Early treatment
- Right treatment to the right patients
- Treatment earlier in causal chain of disease
- Fewer delays in the care delivery process
- Less invasive treatment methods
- Faster recovery
- More complete recovery
- Less disability
- Fewer relapses or acute episodes
- Slower disease progression
- Less need for long-term care

"The contributions of clinical laboratory screening and diagnostic tests to the health system goals (listed in Box 1) are substantial. As an essential component of high quality of care, laboratory tests are used for much more than diagnosis of disease in symptomatic individuals. ***Laboratory testing is an integral part of many medical decisions, providing clinicians with often pivotal information necessary for prevention, diagnosis, treatment, and management of disease. Despite the extensive role of laboratory medicine in informing medical decision-making,*** *in 2007,* ***spending on*** *Part B* ***laboratory services was*** *$6.8 billion or just 1.6% of total Medicare expenditures and* ***2.3% of national health care spending. Significant contributions of laboratory medicine remain untapped.****"*

"The value of laboratory medicine is realized through its many roles in patient care. These include ***screening of asymptomatic individuals to identify risk for developing disease, detecting disease at the earliest stages before symptoms occur, selecting safe and effective treatments, planning disease management strategies, estimating treatment response throughout the course of care, identifying threats to patient safety and public health,*** *such as hospital-acquired infections (HAI),* ***protecting the blood supply and transplant recipients from harmful pathogens, and drugs of abuse testing to support clinical care and assure public safety****. These aspects of value can be expressed along a continuum of care such as is listed in Box 2."*

BOX 2: Laboratory Tests in Clinical Decision-Making

- Screen for disease
- Screen to determine risk for developing disease
- 'Rule in' of a diagnosis
- 'Rule out' of a diagnosis
- Start an intervention
- Adjust an intervention
- Stop an intervention
- Assess efficacy of an intervention
- Assess compliance with an intervention
- Assess prognosis

*"****Laboratory medicine also is important to clinical guidelines****. As described in our 2005 report, a search of clinical practice guidelines across 23 main condition/disease categories found that* ***37% focused on or involved laboratory tests****. Increasingly,* ***the objective, scientific data produced by clinical laboratory tests is used to measure provider performance*** *(individual and organizational) as well as to* ***implement value-based purchasing that aims to optimize use of health care resources and decrease short-, medium-, and long-term costs of care****."*

ANNEXURE D

Quality Assurance Practices – Experiences of Laboratories

The increasing awareness of the costly personal and economic impact of medical errors on patient safety has focused a spotlight on quality management in health care services. In the present environment of limited resources, quality cannot be taken for granted by those who fund, receive, and provide laboratory services. Our historical perspective of quality control and quality assurance must be superseded by a more global view of internationally accepted quality activities applied to a laboratory's scope of work.

An integrated Quality Management System provides an opportunity to deliver consistent, high-quality, and cost-effective laboratory services.

Although some laboratories are working successfully at the level of a Quality Management System, in much of the world, many laboratories are operating at or below the stage of quality assurance. The need to upgrade to a Quality Management System approach has become evident from worldwide reports that describe medical errors in present-day health care systems and from reports of the cost of both good and poor quality on laboratory operations. The best contribution a laboratory can make to reducing errors that can or may cause harm is to understand and document its processes, train staff to competency in following those processes, identify problematic processes, and improve processes where problems exist.

The foundation of a Quality Management System provides a platform for continuous improvement and further transition up the quality hierarchy. With an integrated Quality Management System in place, the following outcomes can be greatly enhanced:

- Ability to reduce or eliminate error
- Likelihood of meeting customer expectations
- Potential for successful governmental and accreditation assessments
- Sustainable attainment of quality objectives

Accreditation to a global standard, such as ISO 15189 provides a platform for recognizing quality and competency in laboratories.

PATHCARE ASSISTANCE WITH QUALITY ASSURANCE AND QUALITY OF CARE IN THE NHI

1. Training in Quality Management

PathCare was the first laboratory in Africa to be accredited to ISO standards by SANAS in 2000. We have more than 10 years' experience in implementing an integrated Quality Management System, and can offer training in this regard. SANAS (The South African National Accreditation System) is currently the only accreditation body in South Africa responsible for carrying out accreditations in respect of conformity assessment, calibration and good laboratory practice. Many **PathCare** staff members are certified SANAS assessors, and as such could provide valuable input into the structure of accreditation/ conformity assessments in South Africa. Furthermore, **PathCare** has experience in international quality management organizations and committees, such as ISO and CLSI, and thus has much to offer in quality management expertise.

Currently **PathCare** runs several courses in quality assurance and quality management; such as Quality Control, Method Validation, Total Quality Management and Internal Auditing Techniques. We can offer training at any level of Quality Assurance and Management, from basic primary health facilities to advanced healthcare settings.

2. Performing GAP analyses to benchmark level of quality in health care facilities

PathCare has vast experience in undertaking GAP analyses and implementing effective laboratory and quality models in

laboratories in South Africa, Namibia, Kenya, Nigeria, Ghana, Ethiopia and Zimbabwe. We understand the challenges that different countries undergo in terms of implementing quality laboratory services, and can assist with performing GAP analyses, training and other benchmarking activities in healthcare facilities in resource-constrained environments.

3. Assistance with delivery of an integrated Point of Care infrastructure in South Africa to assist with primary health care delivery

One of the strong focuses in the NHI Greenpaper is the need for quality services at the Primary Health Care level. As a long standing accredited facility, **PathCare** has the expertise to assist with building an effective laboratory service model at Primary Health Care level. The best option at this level would include Point-of-Care (POC) instrumentation. **PathCare** has years of experience with validating and selecting fit-for-purpose POC instrumentation, as well as links with world standards organizations, such as ISO and CLSI, and can assist the Department in this regard. Furthermore, POC services have different working models versus main stream laboratory instrumentation, and training and effective roll out of this service is crucial, which **PathCare** is once again able to offer its assistance.

4. Assistance with method harmonization in the South African healthcare framework

PathCare has vast experience in the field of validation and harmonization of methods in clinical laboratories, to ensure that all patients receive a standardized, world class laboratory service in South Africa.

We can assist with, and collaborate in, the drafting of technical and quality management guidelines, to provide a standardized level of quality healthcare services in SA.

ANNEXURE E

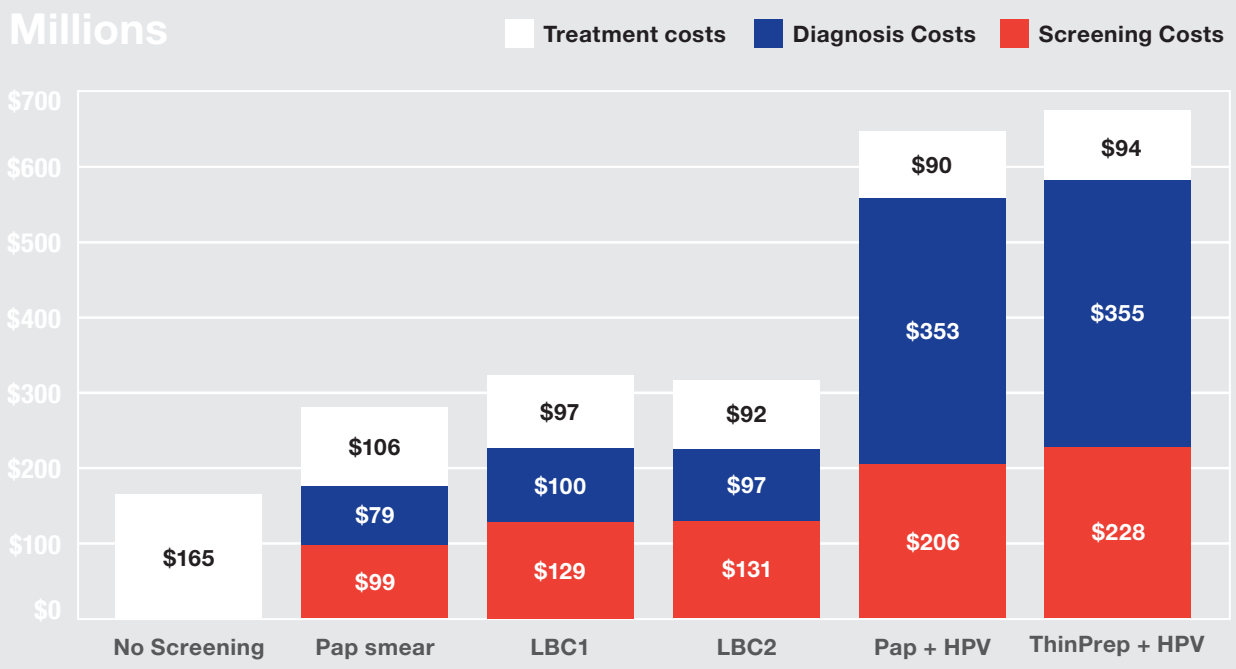
Appropriateness of Care

Appropriateness of Care entails patients getting the right treatment at right time for right condition at right place. Evidence-based clinical guidelines, protocols and algorithms can provide invaluable assistance in ensuring appropriateness of care. **Appropriate use of pathology early on in the diagnostic algorithm has been shown to lessen down-stream costs resulting from complications of delayed and/or poor clinical management.** This is illustrated in the example below where treatment costs are reduced for Cervical Cancer using Laboratory cytological screening methods, such as PAP smear and Liquid Based cytology:

Total Costs Across Managed Care Lifetime (USA)

A HEALTH ECONOMIC MODEL TO DETERMINE THE COST-EFFECTIVENESS OF CERVICAL CANCER SCREENING METHODS

Erik K. Gemmen, MA[1], Rose E. Blackburne, MN, FACOG[2], Andrea J. Ulrich, BA[1], Anke K. van Engen, MS[3], Karent L. Partlow, BS, BA[1]



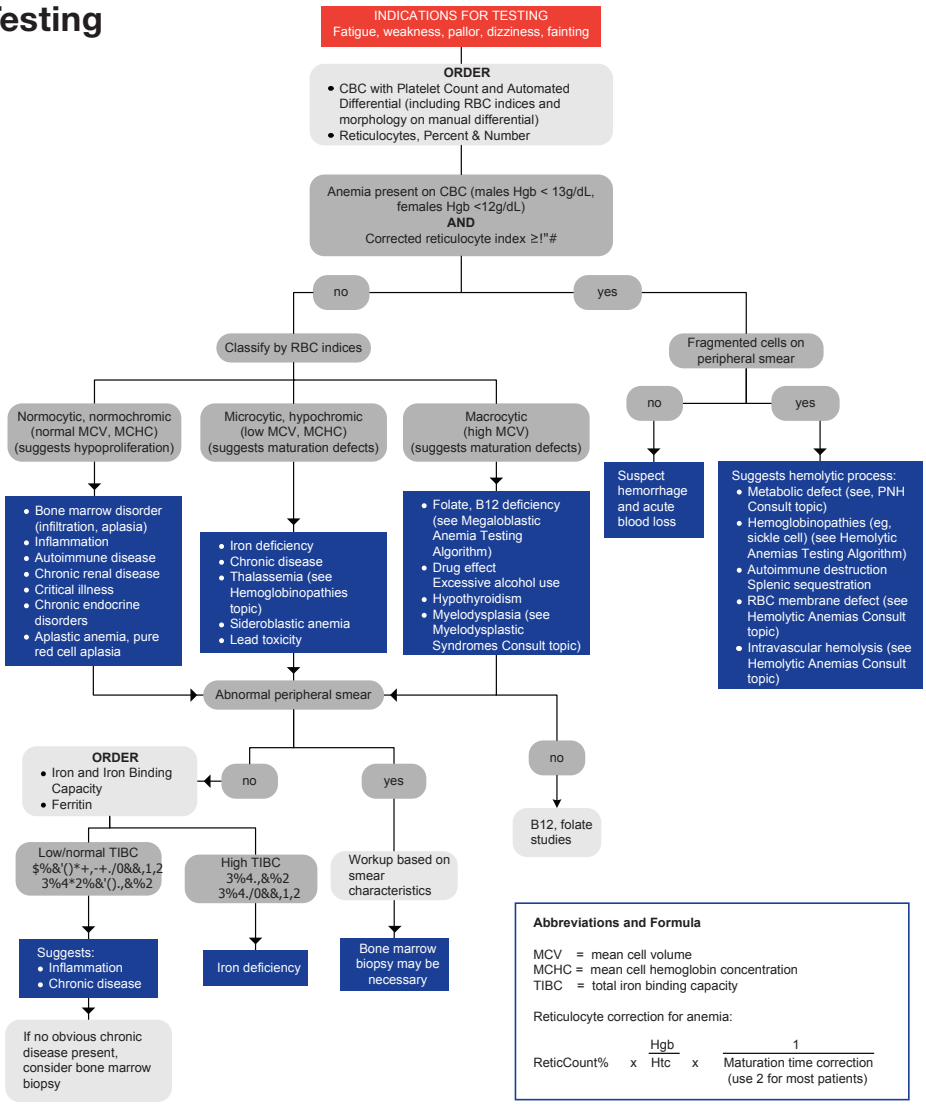
Discounted Total Costs
(100,000 women across managed care lifetime)

Further evidence presented regarding early use of laboratory screening methods is contained in the "National Institute for Clinical Excellence (NICE) Technology Appraisal Guidance 69: Guidance on the use of liquid-based cytology for cervical screening, October 2003":

- "At each screening interval LBC dominated the Pap smear as it was **less costly and more effective**.
- 3-yearly screening with LBC was found to be a cost effective alternative to 5-yearly Pap screening, with an incremental cost effectiveness ratio below £8000 per life-year gained.
- The cost effectiveness of LBC screening at different intervals was compared. The incremental cost-effectiveness ratio of moving from 5-yearly to 3-yearly screening with LBC was £9621 per life-year gained.
- **Conventional screening** with the Pap smear at 5-yearly intervals is **extremely cost effective compared with no screening, at a cost of £372 per life-year gained**."

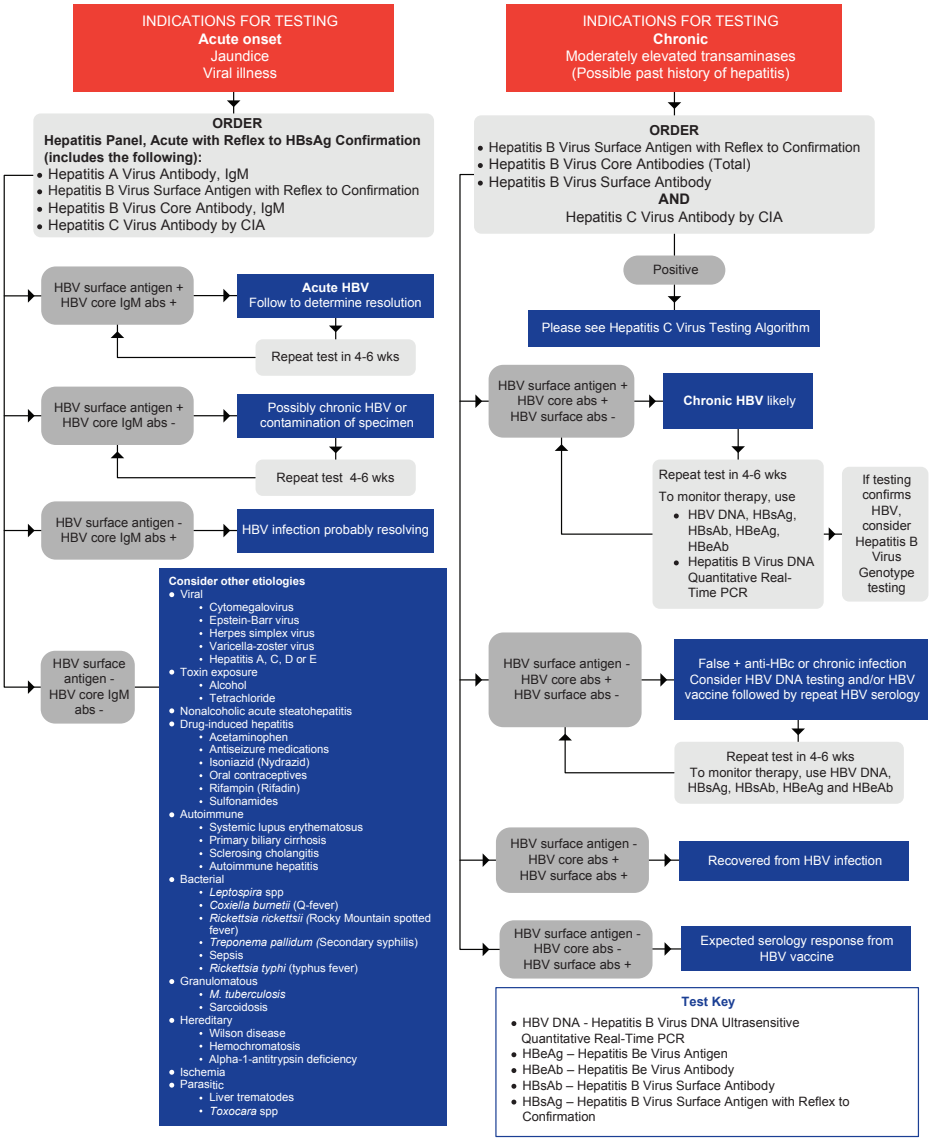
Evidence-based guidelines and algorithms for symptom complexes at all levels of care would provide guidance for step-wise appropriate and judicious use of laboratory investigations. Examples of such algorithms include the investigation of Anaemia (a common condition in SA), which is tabled below:

Anaemia Testing



A further example is the investigation of Infectious diseases such as jaundice and Hepatitis, in particular Hepatitis B:

Hepatitis B Virus Testing



Not only can laboratory investigations assist in appropriate early diagnosis and guidance as to appropriate treatment, but can also assist in measuring appropriateness of provider performance, as indicated in the article by the Lewin Group (Inc) in September 2009 entitled **"The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement"**:

"Laboratory medicine also is important to clinical guidelines. As described in our 2005 report, a search of clinical practice guidelines across 23 main condition/disease categories found that 37% focused on or involved laboratory tests. Increasingly, the objective, scientific data produced by clinical laboratory tests is used to measure provider performance (individual and organizational) as well as to implement value-based purchasing that aims to optimize use of health care resources and decrease short-, medium-, and long-term costs of care."

ANNEXURE F

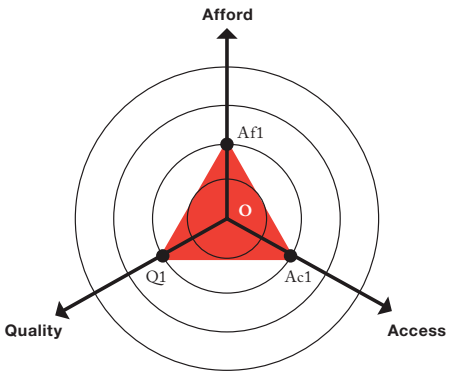
Affordability

Affordability is a key concept when looking at the sustainability of a health system. It is, however, intrinsically related to two equally important goals of any health system, namely, quality and accessibility.* Both quality and access are key NHI principles, and care should be taken that the balance between these three concepts is maintained. The three concepts can be defined as follows:

- Affordability is generally considered to be available income divided by price
- Quality is a combination of durability, effectiveness, efficiency, practicality and appropriateness
- Accessibility is the relative or absolute ease of access to the product

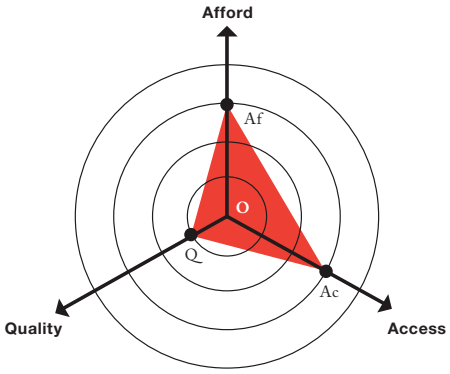
The following illustrations by Tony Twine indicate the sensitive balance between the concepts when applied to health systems decision-making:

The AQA Principle



Mr Twine argues that the benefit of healthcare (the triangle) has to be expanded by concentrating on all three principles. Concentrating only on affordability, whilst aiming to increase access, for example, will have the following effect:

Finite Resources – Something has to Give



* See presentation by Tony Twine, BHF Conference, July 2007.

A key concern in relation to the NHI Green Paper is that the level of affordability is not known, and neither is accessibility, i.e. to what services and goods (and for what conditions) patients would have access. In contrast, the meaning of quality is being defined, and the institution of the Office of Health Standards Compliance, as well as talk of the development of health outcomes measurements (to be developed by the Health Data Advisory Coordinating Committee (HDACC) and centres of clinical excellence). Unless properly defined and calculated, the objective of quality may be compromised by increased demand for access to healthcare and limitations in affordability.

Price controls have been mooted as a way to increase access and affordability. The focus should, however, be on expanding the area covered by the triangle, by all three principles moving outwards towards the perimeters represented by the circles in the figure. Mr Twine proposes that this be done by means of "adding of economic energy … such as Increasing income, Investing in products and systems and investing in skills creation." It is noted that the last-mentioned driver of economic energy is found in the Human Resource for Health Strategy document of October 2011. However, little is said within the NHI debates on how it links to increased income and investment in products and systems. An over-regulation of prices may hamper one of these key drivers, i.e. investment on products and systems, which are key in ensuring a responsive system of pathology services, and which drives economic growth in the health sector.

ANNEXURE G

Efficiency and Choice

The Green Paper does not define efficiency, although it is stated as a key principle. There are many types of efficiency, namely[1]:

- Technical – produce a given quantity of **output** using the least cost combination of inputs*
- Allocative – with given resources, it is not possible to make one person better off without making another worse off (Pareto optimality)*
- Social efficiency (e.g. by means of progressive taxation systems), Horizontal and Vertical efficiency (used in competition law contexts)

The IMF report referred to below uses a source that measures efficiency in terms of quality of life increases, and life expectancy increases, noting that evaluation of efficiency will depend on what the desired outcomes or outputs are.

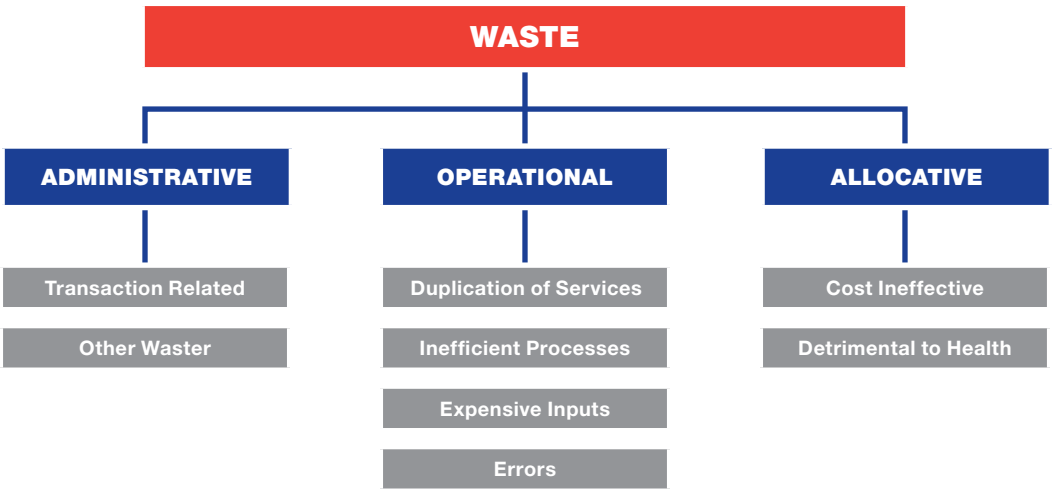
This approach therefore brings efficiency closer to the NSDA (National Service Delivery Agreement) outputs expected of the department of health, which include "to increase life expectancy", and "to decrease maternal and child mortality" as the measured outputs.

We are concerned that the Green Paper only focuses on two types of inefficiency:

1. duplication of services (which it proposes to address by means of referral systems and adherence to protocols),
2. and expensive inputs (which it refers to in its statements on originator medicines, for example).

The Green Paper also briefly refers to a third inefficiency, namely, cost-effectiveness.

The following extract from the Australian 2009-report *"A Healthier Future for All Australians: Final Report"*, as adapted by Childs gives a more complete picture of the analyses that should accompany the implementation of the principle of efficiency within the envisaged NHI:



A key reform proposed by the Australian report was efficiency by means of having records and giving patients control over information relating to their healthcare[2]. It is obvious that the data and systems in place at diagnostics and pathology level are critical in order to minimize both operational and allocative waste (inefficiencies).

A recent IMF report[3] examines, amongst others, healthcare spending and efficiencies. It notes that "cutting the efficiency gap of OECD countries in half, for example, would increase life expectancy by over one year. Achieving this through higher spending, in contrast, would require an increase of over30 percent." This means that, as much as focus is on pricing and budget, efficiency should be the overarching judge of whether services are expensive or not, and affordable or not.

The report also evaluates the efficiencies gained by various types of health sector reform strategies (including cost-containment interventions), the results of which state that "**substantial reductions in Excess Cost Growth (ECG) could be obtained from extending market mechanisms (-0.50), improving public sector management and coordination (-0.30) and strengthening budget caps (-0.24)** — relative to the 1.0 average ECG. **Some measures appear ineffective in controlling health spending, e.g., price controls are associated with higher excess cost growth (+0.11).**"[4]

In discussing each of the successful and less successful interventions, the report notes the following on extending market mechanisms:[5] "The econometric analysis shows that a one-unit increase in the indices for choice of providers and insurers, private provision, and the ability of insurers to compete would altogether reduce excess cost growth by about 1⁄2 percentage point. 19 Event studies also find that the growth in public health spending as a share of GDP slowed after reforms that increased the use of market mechanisms, especially relative to countries not adopting them…"

For countries such as Australia, Belgium, Canada, Denmark, Finland, Iceland, Ireland, Italy, Korea, Luxembourg, New Zealand, Norway, Portugal, Spain, Sweden and the United Kingdom the IMF recommends "Increase the degree of user choice over insurers (including not-for-profit public insurers). For example, by increasing the number of insurers. Most relevant for Public Contract health care systems" as a specific market mechanism relating to choice of insurers, with "Choice Among Providers" being recommended for Austria, Denmark, Finland, Greece, New Zealand, Portugal and Spain ("Allow greater patient choice over primary care physicians, specialists and hospitals, even if some limitations remain"). The IMF report and the Australian Report confirm the importance of Health Information Technology to improve efficiencies. Too little is, however, currently known for us to comment on media reports relating to work undertaken in this field in preparation of the NHI. It is hoped that this work would soon be made public, so as to ensure wider participation and comment on this important element.

1 Presentation by Barry Childs "A Tale of Two Sectors: Comparing efficiencies between the public and private sectors" BHF Annual Conference, 2009.
2 Page 129 of the report proposes a system of e-health and e-records, aimed at increasing patient responsibility for the health, which is an additional advantage to the obvious elimination of wastage through duplication.
3 IMF Macro-Fiscal Implications of Health Care Reform in Advanced and Emerging Economies, 28 December 2010 available at http://www.imf.org/external/np/pp/eng/2010/122810.pdf.
4 Page 19 ff.
5 Page 26.

ANNEXURE H

Efficiency Through Competition

To be efficient in competition law terms, NHI policy should increase both allocative and productive efficiency, and encourage efficiency.[1] As the enhancement of competition law is a stated government objective, and key in policy documents such as the Industrial Policy Action Plan and the New Growth Path, NHI associated regulatory interventions should be tested in terms of its impact on competition law in general, and efficiency in particular.

Economic theory[2] states that competitive rivalry between firms may take place in terms of price, quality, service or combinations of these and other factors which customers (i.e. the patients benefitting from the NHI) may value. Effective competition occurs when:

- There are numerous competitors
- One or a few firms do not dominate the market; and
- Entry by new competitors is relatively easy.

Effective competition provides consumers with **lower prices, a wide range and diversity of products and services (choice), better quality products and services and new and improved products and services over time (innovation, also called dynamic efficiency)**. It therefore encourages and promotes firms' productivity and efficiency to meet the existing and future needs of customers. By definition, single suppliers can therefore not be competitive, and would have no incentive to be efficient, or competitive in terms of price, quality, service or innovation.

Responsiveness to the healthcare needs in a particular area would be important in the NHI, and a system that eliminates all competition in an area or region or province would have long term negative sequelae to quality first and **cost-effectiveness over the longer term**. And as is indicated by competition law theory, competition should not be based solely on price, as this may lead to the elimination of quality provider and eventually a service which promotes under servicing, low quality, cheap products. Efficiency relates to output, and output (see Annexure F above) relates to that expected of the Department of Health in terms of increased life expectancy, for example.

Multiple providers in a system of competition based on quality as an outcome of efficiency should be the objective. Fotaki et al in their paper[3] *"What benefits will choice bring to patients? Literature review and assessment of implications"*[4] concluded in their assessment that choice simply **"stimulates providers to improve quality of care"**.

Competition law also provides remedies for competition law violations, such as exploitation of consumers, exclusion of competitors and unfairness of competition.

The proposal in the Green Paper that District Health Authorities will contract service providers is welcomed. This, coupled with the demands of efficiency and the IMF's findings on the successes of contracting as a cost-containment measure in health systems, bodes well for a competitive system based on facility, or district basis. Using an all-or-nothing tender basis could lead to decreased competition, lack of choice and eventually worsening the cost-effectiveness of laboratory services. Contracting that allows multiple service providers in the pathology laboratory industry would allow for choice and competition based on service.

The UK NHS as a system that enhanced competition through choice

An important theory in economics is the "choice theory". This theory demonstrates that:

1. Consumers make certain choices in a free market system
2. Factors drive the consumers to make these choices.
3. Choice plays a key role in improving consumer access to goods.
4. Consumers will look for substitute goods in place of over-priced or poorly produced original goods.

5. Consumer behaviour is perhaps the most important part of choice theory in economics". [5]

Choice is key to creating competition. Competition is critically important to ensure quality, efficiency and an adequate supply of services. The British NHS is the largest National Health system in the world and one of world's biggest employers. It has recently introduced reforms to improve competition to ensure efficiency, control costs and improve patient choice. A central component of these reforms was the "NHS-Choices" initiative. The size and scale of the NHS choice initiative highlights the importance placed on "choice" by the NHS to achieve efficiency and patient satisfaction.

NHS patients were given extended patient choice in 2006: "Where appropriate, people have the choice of at least four providers when referred for planned hospital care. In May 2006, an Extended Choice Network is launched. This allows patients to choose from NHS foundation trusts and independent sector treatment centres, in addition to local options. In August, the scheme expands further, with more independent providers added." This was expanded to free choice in 2008: "Patients referred by their GP for their first consultant-led outpatient appointment can choose from any hospital or clinic that meets NHS standards"[6].

The NHS reforms that allowed choice to stimulate competition demonstrated improved efficiency, quality and decreased mortality. This finding has been supported by research[7/8]. The impact of the introduction of competition has had a positive effect. Two recent papers by Zack Copper and colleagues from the London School of Economic confirmed the positive impact of these reforms. They concluded that:

1. Competition prompted public hospitals to improve their productivity by decreasing their pre-surgery length of stay of stay.[9]
2. Competition caused "mortality rates to fall more quickly (i.e. quality improved) for patients living in more competitive markets after the introduction of hospital competition in January 2006."[10]

While the NHS needed reform to introduce competition to improve quality and efficiency, we have an opportunity to ensure that our South African NHI model takes cognisance of the need for competition and incorporates the principles of competition in its design from the start. This will be achieved by having more than one supplier per region contracted to deliver services. Simply put our NHI cannot afford not to improve competition for the delivering the health care to South African.

Examples from other industries within South Africa A single supplier or a supplier protected by regulation will impact the quality of service, the cost of service and the adequacy of supply. In South Africa, we have recently experienced the impact of limited competition with significant impacts.

For example, we have seen limited competition in telecommunications:

"[The] high cost of Internet access is a major point of consumer frustration in South Africa. Telkom's monopoly over fixed line provision and international access is often pointed out as the primary reason for the high costs of telecommunications. In light of the high cost of entry, many broadband users have settled for cellular alternatives."[11]

Another example is the limited competition in the supply of electricity, which has also had a significant impact on South Africans, resulting in, amongst others, rolling black-outs. The Government in its national response to this crisis identified several supply side interventions as being necessary to ensure an adequate electricity supply. Interventions included "new build and Return-to-Service plants (de-mothballing)"[12] and an opening up of energy sources to include smaller projects that include wind- and solar as energy sources.

1 Geradin 'Efficiency claims in EC competition law and sector-specific regulation' paper presented at First Workshop on Comparative Competition Law, Florence, November 2004.

2 Summarised by Holland "Economics of Competition law in South Africa" http://www.pricemetrics.co.za/sg_userfiles/Economics_CompetitionLawSA.pdf.

3 What benefits will choice bring to patients? Literature review and assessment of implications Marianna Fotaki, Martin Roland1, Alan Boyd, Ruth McDonald, Rod Scheaff2 and Liz Smith, J Health Serv Res Policy July 2008 vol. 13 no. 3 178-184

4 J Health Serv Res Policy July 2008 vol. 13 no. 3 178-184.

5 Wikipedia – Choice theory – (Accessed 31/10/2011)

6 NHS Website – The History of the NHS – (Accessed 02/11/2011)

7 Public Sector Hospital Competition, New Private Market Entrants and Their Combined Impact on Incumbent Providers' Efficiency: Evidence from the English National Health Service, September 2011, Cooper et al, The Centre for Economic Performance, The London School of Economics

8 Does Hospital Competition Save Lives? Evidence From The Recent English NHS Choice Reforms, December 2009, Zack Cooper, Stephen Gibbons, Simon Jones and Alistair McGuire The Centre for Economic Performance, The London School of Economics

9 Public Sector Hospital Competition, New Private Market Entrants and Their Combined Impact on Incumbent Providers' Efficiency: Evidence from the English National Health Service, September 2011, Cooper et al, The Centre for Economic Performance, The London School of Economics

10 Does Hospital Competition Save Lives? Evidence From The Recent English NHS Choice Reforms, December 2009, Zack Cooper, Stephen Gibbons, Simon Jones and Alistair McGuire The Centre for Economic Performance, The London School of Economics

11 Wikipedia – Telkom (Accessed 21/10/2011)

12 National Response To South Africa's Electricity Shortage, January 2008

ANNEXURE I

Human Resources – Training and Capacity Development

The *HRH Strategy* (table 19, page 134 – 135) lists the "base year" and "2011" gaps in critical health professionals, as far as laboratory medicine and pathology is concerned at over 5000, with shortfalls to be addressed as follows by 2015, 2020 and 2025 respectively:

Staff Name	Base Year	2011	2012	2015	2020	2025
Medical Technologists	-4,738	**-3,884**	**-3,306**	**83**	**1,026**	**1,1274**
Pathology: Anatomical	-98	**-96**	**-93**	**-69**	**-35**	**-6**
Pathology: Chemical	-50	**-48**	**-47**	**-34**	**-18**	**-2**
Pathology: Clinical	-13	**-13**	**-13**	**-10**	**-5**	**-2**
Pathology: Forensic	-136	**-147**	**-158**	**-144**	**-88**	**-15**
Pathology: Haematology	-64	**-62**	**-60**	**-44**	**-22**	**-4**
Pathology: Microbiology	-64	**-59**	**-54**	**-35**	**-15**	**-3**
Pathology: Virological	-19	**-18**	**-16**	**-11**	**-6**	**-2**

The time it takes to train such healthcare professionals are to be considered, as well as the capacity to train. To train a pathologist takes 14 years. To generate this number of pathologists and technologists would require co-operation of the private sector, and an increase in pathology registrars from as early as 2012.

Over the past 5 years, public and private laboratories have successfully trained 957 Medical Technologists, 1127 Medical Laboratory Technicians, 313 Phlebotomy technicians, and 220 Laboratory Assistants. NHLS has trained 152 Pathologists over the past 5 years. This represents a total of 3000 health professionals in 5 years. The involvement of the private sector in the training of all healthcare professionals, including pathologists, can be optimised in order to meet the stated demand for healthcare professionals in pathology.

PathCare remains committed to fulfil, and enhance its role in education and training.

Of particular importance is the training of phlebotomists and nurse practitioners, upon whose shoulders the correct collection of specimens and pre-laboratory procedures, and hence correct diagnosis (and quality of diagnostic outcome), rest. Within hospital-settings near-patient testing also takes place through the use of a Haemoglobin meter, a Glucometer and rapid tests available for HIV and Urine-dipsticks that nurses will use at their discretion within the unit to determine problems to be reported to the doctor. Within primary care settings nurse practitioners (in many cases without the assistance of a medical practitioner) undertake or facilitate HIV-related (diagnostic and treatment-regime-specific) - and STI (e.g. syphilis) tests. The introduction of Nurse-Initiated

and Managed ART (NIMART) will put additional pressure for training in this field on such nurse practitioners. Within the field of family planning tests include the RPR or VDRL, TPHA or FTA may be required to ensure reproductive health along with PAP smears. In the field of TB, apart from sputum samples, the histologic examination of lymph-node biopsy and non-specific tests such as FBC and LFT may also be required by the nurse. The management of chronic diseases also imply regular tests, such as diabetes and epilepsy management. Although the Essential Drug List and Standard Treatment Guidelines make reference to key diagnostic points in the treatment of listed conditions, the description of laboratory tests and near-patient testing (including verification of rapid and other point of care results) can be enhanced.

The role of the nurse in South Africa is determined by the Nursing Act (No 33 of 2005) and the Regulations developed by the South African Nursing Council (SANC) required to implement the Act. To date regulations essential to the implementation of the Act and to determine the Scopes of Practice, for the different categories of nurse, have not been determined. This means that no criteria and competencies have been set for nurses that fulfil the roles outlined above. This is a key prerequisite for the implementation of not only the Human Resource reforms, but for the successful expansion of quality diagnostic services into a system of enhanced healthcare cover. Furthermore, it appears that the skills levels of the nurses involved in the above activities have not been monitored or evaluated and the success of their management of pathology and near-patient testing on patient outcomes are not known.

Little is known about the structures proposed in the *HRH Strategy* document (pages 80 and 106 – 109), and further engagements and consultation would be required in relation to the various Centres, Committees and working groups proposed, prior to implementation. For example, it is possible that a private laboratory may constitute a Centre of Excellence within the context of the *HRH Strategy*. Due to its extensive involvement in training, **PathCare** requests to remain involved in the HRH developments as it takes place within the context of securing adequate human resources for a future NHI.

As far as the licensing of medical practitioners (as mooted in the *HRH Strategy*) and accreditation of practices for NHI (as set out in the Green Paper) is concerned, it should be noted that the quality of facilities and the availability of appropriately qualified staff are regulated by means of SANAS accreditation (which it is hoped will be adopted for the accreditation of laboratories by the OHSC), and that all aspects of professional training, education and practice are subject to the regulatory control of the Health Professions Council of South Africa (HPCSA) in terms of the Health Professions Act of 1974.

ANNEXURE J

Appropriate Pricing

The Green Paper refers to the 2008 World Health Report* as warning of the trend of "allowing unregulated commercialism" in health systems. It is important not to confuse the elimination of unregulated commercialism with moving to a single supplier of a service within a specific region (in effect eliminating competition), or as justification of any particular mode of price regulation or control. The relative effectiveness of various types of cost-containment measures (including price regulation) are referred to in Annexure G and merits careful consideration not only for its impact on the cost-effectiveness and efficiency of the system, but also in terms of unintended consequences in terms of the availability of healthcare services (including professionals).

Various concepts require clarification, and must be separated in view of a rational and coherent approach to the NHI:

- The price (unit cost) of specific goods and services;
- The cost of certain goods and services to districts (including, for example, cost to hospitals or clinics);
- The costs of goods and services to provinces;
- The costs of goods and services to the NHI (which would include, for example, the costs of delivery through all health facilities – public (provinces) and contracted in private sector);
- Budget impacts over the short- and longer term (affordability and sustainability); and
- Cost-effectiveness.

Interventions at unit price level may not necessarily yield savings at budget-impact level, or be cost-effective when viewed within the context of the return on investment generated by a particular (albeit perhaps relative expensive diagnostic) intervention, for example. The availability and choice of goods and services at facility level are often limited by available budgets at such facility and the healthcare needs of populations served, whereas the cost to the NHI could include larger scale trade-offs that would include administration and non-healthcare services, for example.

The levels at which professionals, whether employed or contracted into the NHI, are reimbursed remain critical and merits thorough discussion and analysis. These levels could be determined by means of price regulatory mechanisms (central bargaining, price setting by an independent body, price benchmarking, etc.) or by the free market (with certain market-related controls for example). Centralised price regulatory mechanism for professional fees within the NHI framework should consider economic realities and ensure an appropriate ROI (return on investment) to ensure that continued investment is made in capital intensive health services like pathology. This can only be achieved if the price setting authority is independent and the process conducted within a robust financial framework that recognises the importance of economic returns for sustainable service delivery. The alternative is to allow market forces to determine price levels and end-costs to the system. The IMF report referred to in Annexure G mentions the extension of market mechanisms, such as reforms that operate on the nexus between supply and demand. Examples include the creation of internal markets, separating the purchase of health services from provision (thus allowing competition among providers), and promoting patient choice to determine prices.

The Green Paper proposes two systems at which the reimbursement of healthcare professional services could be set, viz.:

- Capitation; and
- Global budgets moving to DRGs (Diagnosis-Related Groups)

In neither case is it really clear if, and exactly how, pathology services would be included in these reimbursement models and **PathCare** proposes the engagement of stakeholders in these important matters.

While fee-for-service raises concerns as to over-servicing, the opposite is true of a capitation model, i.e. Under-servicing

* World Health Organisation, The World Health Report 2008, page 11

may be promoted. This is well described in international literature. In a capitation environment high usage of laboratories would result in high cost without commensurate income and may cause laboratories to be unsustainable. For both models, (fee-for-service or capitation) testing should be decided according to evidence based published data and commensurate clinical guidelines. In any setting (public or private sector) the cost of rendering the service must be factored into the remuneration. In **PathCare's** experience capitated models within the field of pathology are particularly problematic from both a cost-based perspective, as well as from a health outcomes perspective where prevention, early detection and monitoring militates for increased spending on pathology.

PathCare proposes a model where contracted-in pathology providers have a multitude of pricing tools to provide services to facilities in a district in a range of "fit-for-purpose" and efficient way. This is flexible, and would even allow mid-contract negotiations, should the environment so require (e.g. an outbreak of cholera, for example). In some cases, such as rarer disease, or where tests have to be custom-made, this could be performed on a fee-for-service model, whereas tests associated with HIV services in clinics might be bundled, or provided on a capitated basis. The point is that pathology services cannot be "pinned down" to the extent that there would be a "per patient per month" or an "amount per disease condition" cap on such services. Capitation of services eliminates the perversity for over servicing but creates the risk of under servicing. In a service like pathology where the focus is on screening for disease and measuring disease progression the perversity of under servicing created by capitation could be particularly problematic.

A similar challenge occurs with the Green Paper's envisaged performance based reimbursement, which may lead to providers, clinics and hospitals not ordering the tests required, in order to keep below upper levels set for performance. **PathCare** proposes that any performance-based reimbursement model considers the knock-on effect of other disciplines on pathology, and that a rational, and health-outcomes based approach be followed as far as pathology itself is concerned.

Little is known on the specific DRG models currently under consideration. As a prospective reimbursement system, based on historical data, it supposes a relatively well-developed health- and treatment data-set, and a clear coding system. Healthcare professionals have been grappling with Coding issues for many years, and it is proposed that such a significant change in the manner in which budgets are allocated to health facilities be undertaken in consultation with the affected professionals. The move from global budgets to DRGs as mechanisms on which facilities will obtain funding from the NHI should also be carefully mapped out. A DRG system that does not allow for adequate remuneration of professional services rendered to the NHI could have a severe impact on the availability of healthcare services. Discussion on the entity that "controls" payments made to service providers under a DRG system is also critical. Insofar as the idea of all healthcare professionals being employed by health facilities (public or private) has been advocated, **PathCare** urges consultation with all stakeholders and consideration of the current legislative frameworks, such as the Health Professions Act of 1974.