



## Transformation of laboratory services

*A comprehensive clinical laboratory service is indispensable to proper patient care. It plays a part in making a diagnosis and influencing treatment decisions in patient care and has public health value. Public health sector laboratory services are very fragmented and range widely in quality. There have been attempts over the years to rationalise and restructure these services and to upgrade the quality where it is poor but there have always been reasons why this has not occurred. The fragmentation of the services has resulted in a loss of economies of scale, especially where highly specialised equipment, expensive reagents and unique skills are concerned.*

*In this chapter, the history of the many players in the provision of the services that is relevant to the developments and the failure to rationalise the services in the past is briefly discussed. For many years all roleplayers have recognised the need to improve the whole laboratory system. Immediately after the 1994 elections the Minister of Health established a commission to investigate the rationalisation and reorganisation of the laboratories. One issue was the joint ownership of the South African Institute for Medical Research (SAIMR) by the Chamber of Mines (CoM). In October 1998 the CoM unconditionally donated their interests in the SAIMR to the government. A Transformation Task Team (TTT) was appointed to make new recommendations for the restructuring of the public health laboratory services. The TTT recommended the establishment of a new parastatal (public entity) and for all public health laboratory services to become a part of that entity. Since May 1999 a Project Implementation Team has been designing the new entity in earnest.*

*The vision is for a single entity that is large enough to derive benefit from economies of scale and therefore to ensure that services can be provided even where they are not independently viable. The control over purchasing services will remain with the clinicians that request laboratory tests. The new entity will employ about 4 500 employees and will have an annual turnover that is expected to be close to R1bn within the next two years. The National Health Laboratory Service Bill has been adopted by Parliament.*

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*The staff who currently work in the laboratory services of ten different employers have to be transferred to the employment of a single new employer. There has therefore been a very heavy planning focus on human resources issues. The relationship between universities and laboratory services has resulted in a “hybrid model” that is briefly outlined. A ‘total quality management’ (TQM) programme and information technology as supporting processes to the laboratories have also received attention.*

*The chapter concludes with some lessons that can be learnt regarding transformation of government functions and services into a public entity generally and with others that are specific lessons and opportunities related to the laboratory services.*

## Introduction

This chapter has a dual function. It reports on the developments in the public health laboratory arena but it is also a useful case study of the processes that are involved in the transformation of services in the country.

The laboratory service is often taken for granted in a clinical setting. However, a comprehensive clinical laboratory service is indispensable to proper patient care. The services that are offered include consultation on the correct specimen to be collected, the management of the specimen (including its storage, transport, safety and ultimately disposal), the performing of tests on the specimen, the provision of a result and finally the interpretation of that result. So, while the laboratory service is in the business of “providing results” it is also very much a part of making a diagnosis and influencing treatment decisions in patient care. Of course there is also a massive public health value provided by the laboratory services. The monitoring of causative organisms of disease, their vectors and hosts is all part of the work of the laboratory service. The thousands of test results obtained every year provide extensive information about the behaviour of disease.

The medical laboratory services in the public health sector of South Africa are very fragmented and range in quality from the services that one would expect from any world-class accredited laboratories to very poor and unreliable services. There have been attempts over the years to rationalise and restructure these services and to upgrade the quality where it is poor but there have always been reasons why this has not occurred.

The private health sector has an extensive range of private pathology services. This is a very lucrative business in the private sector, reputedly second in profitability to only radiology. The public and private sectors do interact and there are examples of sharing of resources and contracting out to one-another but these arrangements are mostly loose and unstructured, having developed by convenience over long periods of time.

Blood transfusion services and human tissue services are managed as totally different services and are not part of routine diagnostic services. However, the diagnostic laboratories in smaller and more peripheral areas frequently serve as blood product depots and perform the compatibility testing on issued products on behalf of the transfusion services. Blood transfusion services are run by “not-for-profit” section 21 companies. There have, until recently, been several separate companies but there is a process currently underway to unite them all into a single larger service.

Vaccine research and manufacturing was previously also a function of the pathology laboratories, but as described in the chapter, this is no longer the case. Anti sera for the

treatment of snake, spider and scorpion venom are still manufactured by the South African Institute for Medical Research (SAIMR).

This chapter describes the recent developments in the restructuring of the diagnostic laboratory services. The fragmentation of the services has resulted in a loss of economies of scale, especially where highly specialised equipment, expensive reagents and unique skills are concerned. The need and desire to overcome the fragmentation is not new. It has been topical since the early 1970s. Since 1994 (and very intensively since 1999) there has been a concerted effort to restructure the laboratory services. The process is still unfolding so the end result may be different from what is described and anticipated in the chapter.

## Historical background

There are many players in the provision of laboratory and pathology services to the public sector health services. Each player has its own history and the history is relevant to the developments and the failure to rationalise the services in the past. A brief synopsis of each is provided to contextualise the chapter.

### Major Laboratory Services Providers in South Africa

#### South African Institute for Medical Research (SAIMR)

The SAIMR, which provides about half of the country's public sector laboratory capacity, was established by an agreement that was entered into between the Union government and the Witwatersrand Native Labour Association in 1917.<sup>a</sup> In the years preceding this, and from the time of union in 1910, the mining industry had grown very rapidly and there was a need for the mines to ensure that their labour force was healthy. There was also concern about the influence that the growing industry would have on the health of people in the mining areas of the Witwatersrand. The labour recruitment agency, then called the Witwatersrand Native Labour Association, and the government each contributed 30 000 Pounds to the establishment of the SAIMR and the government contributed land in Braamfontein for the erection of laboratories.

Over the years this establishment grew and expanded to include diagnostic services as well as perform the research for which it had been established. The SAIMR also expanded services to all provinces and homelands except KwaZulu and Natal.

The SAIMR also developed significant vaccine capabilities and for many years manufactured all of the country's diphtheria/tetanus (DT), diphtheria/pertussis/tetanus (DPT) and Tetanus Toxoid vaccines, plus others.

When the University of Witwatersrand Medical School was established, the SAIMR became the School of Pathology of that faculty but remained a separate entity owned jointly by the government and the mining industry.<sup>b</sup> The Chamber of Mines eventually became the representative of the mining industry when the Witwatersrand Native Labour Association was replaced by the Chamber's own recruitment agency. The SAIMR Board of Management was jointly appointed by the Minister of Health and the Chairman of the Chamber of Mines until 1998.

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a Founding Statement of the South African Institute for Medical Research, 1917.

b Minutes of the Meetings of the Board of Management of the South African Institute for Medical Research between 1934 and 1936.

## Provincial Departments of Health

There has never been any requirement placed on either the former provincial administrations or the present provincial administrations to use the services of the SAIMR. Three of the four former provinces (Cape Province, Transvaal and Orange Free State) chose to use SAIMR services but not exclusively and Natal chose not to use the SAIMR at all. The three provinces using SAIMR services also established their own laboratories in some hospitals. These were largely, but not exclusively, in the teaching hospitals associated with the medical schools, the University of Witwatersrand associated hospitals being notable exceptions.

## National Institute For Virology (NIV)

The Poliomyelitis Research Foundation was founded in 1948 as a non-government initiative and the laboratory complex developed between 1951 and 1953. On 1 April 1976 the government took over the foundation's activities and the NIV was established.<sup>c</sup>

The "Poliomyelitis Research Foundation" still exists as a research foundation. The SAIMR did not develop any capacity in the Transvaal for virology, and the NIV became the Department of Virology of the University of Witwatersrand.

Since the NIV had been instrumental in the development of polio vaccine there was a plan to establish a polio vaccine production plant at NIV. This was partly erected in the mid 1990's but was never completed.

The NIV is the main virology reference centre in the country and has several WHO accredited reference laboratories, including one of only two bio-level four laboratories in Africa. This is the highest safety status accorded to a laboratory and it provides the environment for scientists to work with highly contagious and dangerous bio-hazardous materials and causative organisms such as Congo fever, Lassa fever, Ebola virus, etc.

## National Centre For Occupational Health (NCOH)

The NCOH was established as the Pneumoconiosis Research Unit of the SAIMR in the 1950s.<sup>1</sup> It was subsequently transferred to the Council for Scientific and Industrial Research (CSIR) and then to the Medical Research Council (MRC). In 1979 the NCOH became a part of the Ministry of Health. This centre has capacity for investigation of occupational diseases and laboratories for occupational environment analysis. Since 1983 it has been associated with the University of Witwatersrand for which it serves as the occupational medicine department. The NCOH was internally restructured in 1997 to accommodate a changing occupational health environment.

## University Pathology Departments

There are eight medical schools in South Africa. Each has a pathology department and laboratories. The medical schools are involved in teaching, research and in the provision of services to the hospitals in which they teach their students. The situation is different in each of the medical schools. The University of Witwatersrand has the SAIMR laboratories in Johannesburg as its major resource, for which the university pays the SAIMR about R4.8m per annum. The University of Pretoria established the Institute of Pathology (UPIP) in the 1920's and manages this within the university, independent of the hospital services. The

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<sup>c</sup> Prof B Schoub, Director of the National Institute for Virology, personal communication.

UPIP “sells” pathology services to the government on a cost-recovery basis according to an agreement that has been amended over the years. The pathology department of the Medical University of South Africa (MEDUNSA) is a part of the GaRankuwa hospital establishment but the laboratories are on the premises of MEDUNSA. The university funds some of its own posts to increase capacity in the pathology department. The University of Natal, University of Orange Free State, University of Cape Town and the University of Stellenbosch pathology departments comprise employees of the provincial Departments of Health, some of whom are appointed as “joint appointees” with the universities in order to provide the teaching and research functions.

### **Homeland Services (now provincial Departments of Health)**

During the apartheid years each homeland had its own Department of Health and each had a need for pathology and laboratory services. There was no prescription on the homelands as to how they would provide the services. Many of the hospitals in the rural areas were taken over from churches and church organisations that had provided their own laboratory services. In some instances the SAIMR was asked to take over the provision of the service. This allowed for an agency arrangement for blood banks to be made available in the laboratories because it was not cost effective for the blood transfusion services to establish separate blood banks in every hospital. However, over the years there was a growing unhappiness with the levels of service that were being delivered and some homelands felt that they could provide the laboratory services cheaper themselves. This resulted in several hospitals setting up their own laboratories, often duplicating the SAIMR laboratories to perform a basic range of common tests. This created animosity and decreased the viability of SAIMR laboratories that needed sufficient volume of the common tests to cross-subsidise the more complex services. By 1994 these services were grossly duplicated and most were very poorly developed. Staff in government hospital laboratories have been finding it more and more difficult to obtain reagents and materials to do their work as provincial budgets have become tighter. The provinces have no means of retrenching these workers and attempts to second them to vacancies in the SAIMR have not been successful.

### **South African Military Health Services (SAMHS), formerly South African Medical Services (SAMS)**

The military have their own laboratory services. These are essentially concentrated in the two major military hospitals in Pretoria and Cape Town. Other military sick-bays and smaller hospitals that are not accessible to these two centres mostly use the services of the SAIMR.

### **Private Sector**

There are five or six large pathology companies in South Africa that have developed from the amalgamation of individual practices. However, there are also many small independent outfits, some run by medical technologists, that sell services in the private sector.

### **Attempts at rationalisation**

The descriptions that are given in this chapter so far are a simplification of the complexities that have developed at a micro-level. For many years all role-players have recognised the need to improve the whole laboratory system. The problem has been the very complexity that needs to be overcome, and the intense vested interests that have become entrenched in the way things are done. People have established laboratories and services that are dependent on their professional and technical inputs and are reticent to change the way that things are

done.

In 1973 a Commission was set up by the Minister of Health under the leadership of Judge Meiring Naude to investigate the restructuring of laboratory services.<sup>1</sup> It must be remembered that this was prior to the 1977 Health Act and the 1919 Act still applied. This also came at a time when the government was gearing up on its homeland policy. The recommendations of the commission were technically sound and called for a single national health laboratory system. However because of the government's drive to establish independent homelands, the opposite happened in the ensuing years and the services were further fragmented.

Immediately after the 1994 elections the Minister of Health established a series of commissions to investigate areas of service provision that had been identified as being in need of rationalisation and reorganisation. Professor van den Ende, the Director of the SAIMR at the time, was appointed to chair a commission to make recommendations to the Minister on the restructuring of laboratory services for the public health sector. The commission made broad recommendations and described the options that were available. However, no consensus recommendation could be agreed upon by the members of the commission.<sup>2</sup> Part of the problem was that the options ranged from total re-incorporation of all laboratory services into the public service, through corporatisation in a parastatal body, to full privatisation of the service. The Chamber of Mines still owned 50% of the interests of the SAIMR and was an important stakeholder in the process.

During 1996 and up to 1998 a Cabinet Committee of the Social Cluster of Cabinet was tasked with engaging the Chamber of Mines with a view to getting their agreement on the establishment of an entirely new laboratory system. During this period the provincial administrations were coming under increasing budgetary pressure and as a result had, amongst other services and suppliers, identified problems with the SAIMR billing system. Their response had been to stop paying while the SAIMR corrected the invoices. This proved to be a complex situation and the practice of not paying for the laboratory service was rapidly entrenched. Concurrently the provincial health departments were putting pressure on clinicians to request less tests, less radiology investigations and to prescribe more judiciously. Volumes of tests decreased at an average of 10% per annum for three years in a row.

By mid-1998 the SAIMR was in financial trouble and it became clear for the first time that if cash flow was not restored the services and the viability of the SAIMR would be compromised. In October 1998 the Chamber Of Mines wrote to the Minister of Health and unconditionally donated their interests (assets and liabilities) in the SAIMR to the government.<sup>d</sup> The Chamber agreed to participate in the management until the end of 1998 to give the government time to reorganise its approach to the SAIMR.

This paved the way for two things. The Minister immediately appointed a Transformation Task Team (TTT) under Professor M. Kallichurum from the University of Natal, who was Chairperson of the South African Medical and Dental Council at the time, as the chair to review the previous recommendations and to make new recommendations for the restructuring of the public health laboratory services. The TTT submitted a report to the Minister and the meeting of national and provincial political heads of health (known as the

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d Letter from the Chairman of the Chamber of Mines, Mr B Godsell, to the Hon Minister of Health, Dr N Dlamini Zuma. October 1998.

Health MINMEC) at the end of March 1999. The second action was that the Minister appointed a new Interim Board for the SAIMR with effect from 1 January 1999 with members and representatives of the Provincial Health Restructuring Committee (PHRC) as the majority of the Board's membership. The task given to the Interim Board by the Minister was to stabilise the financial situation of the SAIMR and to prepare the SAIMR for transformation.

The TTT recommended the establishment of a new parastatal (public entity) and for all public health laboratory services to become a part of that entity. This recommendation was adopted by the PHRC and the Health MINMEC. In April 1999 the Cabinet accepted the essence of the TTT report and decided that a small implementation team should be set up to manage the establishment of the new entity and that an Interim Negotiating Forum be convened with labour representatives of the affected personnel to agree on the labour details.

## **Transformation 2000**

On 1 May 1999 the Minister appointed a leader (the author of this chapter) for the Implementation Project Team and the matter of designing the new public entity began in earnest.

It is important to understand what a "public entity" is. This term replaces the informal use of the word "parastatal" and is defined in the Public Finance Management Act No.1 of 1999 (PFMA). There are three categories defined in the PFMA, viz, constitutional institutions (such as the Human Rights Commission and the Finance and Fiscal Commission), major public entities (such as the Airports Company, Telkom SA Ltd and ESKOM) and other public entities. These other public entities are divided into National Public Entities (such as SA Bureau of Standards and The Medical Research Council), National Government Business Enterprises (such as Rand Water Board) and Provincial Public Entities (mostly agricultural, gambling and liquor boards) and Provincial Government Business Enterprises (eg. Algoa Bus Company). The PFMA defines the responsibilities for all public money. For the first time there is clarity on the reporting structure and accountability of all of the bodies that function outside of the Public Service but use public funds. The advantage of a public entity is essentially that it is able to respond to technical developments in a more flexible manner because decisions are taken by a Board, rather than by Cabinet or Parliament. However, the PFMA is clear that this does not mean that decisions can be taken recklessly.

Notwithstanding the regulatory environment established by the PFMA, each public entity is established in terms of its own law which determines its structure, powers, functions and details of its financing mechanisms. In the case of the National Health Laboratory Service (NHLS), this will be a National Public Entity (Schedule 3A) that derives income from charging fees for services. The entity is to be established as the preferred provider of laboratory services for the entire public sector (all departments in all three spheres of government). It will also be able to sell services to other countries and to private purchasers and will also be involved in research and training in the laboratory environment. The vision is the establishment of a single entity that is large enough to derive benefit from economies of scale and therefore to ensure that services can be provided even where they are not independently viable. The control over purchasing services will remain with the clinicians that request laboratory tests. They will know the costs and, much as is the case in respect of a telephone service, will be charged for only the services that they use. If it is in the interest

of the service the NHLS will be able to enter into partnerships with private service providers.

An organisational structure and staff establishment were developed with the inputs and assistance of the Provincial Laboratory Service Co-ordinators and their working committees in each province. This establishment provides for a Head Office, seven Branches and several specialised Institutes and Committees. Based on available figures of the current staffing levels, it is anticipated that the service will employ something like 4 500 employees and will have an annual turnover that is expected to be close to R1bn within the next two years

The establishment of the NHLS as a public entity is not supported by all stakeholders. There are different reasons for rejecting it. The Western Cape Provincial Department of Health fears that it will lose autonomy, and some university departments of pathology fear losing committed funding to research and teaching. Some detractors criticise the failure to fully privatise the laboratory services and others feel that there is too much emphasis on business practices and commercialisation.

## **Progress to date**

### **Legislation**

The National Health Laboratory Service Bill (Bill 52 of 2000) provides for the establishment of a public entity that functions outside of the Public Service but under the provisions of the Public Finance Management Act, reporting in the first instance to the national Minister of Health. It also provides for the abolition of the South African Institute for Medical Research, the National Institute for Virology, the National Centre for Occupational Health, certain forensic chemistry laboratories and all provincial health laboratory services and for matters connected therewith.

The first draft of the National Health Laboratory Service Bill was circulated for comment to stakeholders in July 1999. There were two subsequent drafts that incorporated many of these comments. The fourth draft was discussed in principle with the Portfolio Committee of the National Assembly whereafter it was published in the Government Gazette for public comment during September 1999. Some 250 direct stakeholder organisations (including all national government departments and provincial Health Departments) were consulted but less than 25 made written submissions.

The Bill was debated in the National Council of Provinces and subsequently in the National Assembly where it was adopted by a majority vote on 12 October 2000. Once the President has assented to the Bill it will be promulgated with a set of commencement dates to enable effective implementation of the new entity, the National Health Laboratory Service (NHLS).

The Bill provides for Rules of the Board. These Rules have the same status in law as Regulations but they are drafted by the Board and not the Ministry of Health. They have to be published in the Gazette by the Board and the Minister of Health still has to approve them before they are effective. Several of these Rules have been drafted and were almost ready for the required consultation processes at the time of writing.

### **Assets**

The Bill provides that the assets of the entities that are being abolished and whose functions are being transferred to the NHLS will be transferred to the NHLS and become a part of the property of the NHLS once it is established. This can be likened to the contribution of equity in the establishment of a company.

In terms of “fixed assets”, the Deeds of all of the buildings and properties that are 100% laboratory service buildings have been researched and documented. Each property has been valued in terms of replacement cost, insurance value and presumed market value. The Registrar of Deeds will be approached by the NHLS Board to transfer the Deeds once the Board members have been appointed. Moveable assets of all of the present authorities have been bar-coded and listed in a single asset register. These registers will be given to the accounting officers of those authorities for them to obtain Treasury approval for the transfer of the assets. The same applies to the transfer of contracts for services and lease agreements for equipment.

### **Structure and Financial Viability**

The staffing structure has been costed (using the estimated average staff costs, historical fixed and variable cost percentages and the anticipated new remuneration and benefits) and amendments to the structure are expected based on these cost estimates.

It is evident from the costing that there are components (certain laboratories and offices) that are over ambitious and over designed, that are therefore not affordable and that are not going to add value to the organisation and its ability to deliver quality services to the public health services. There is likely to be a change in the structure of the organisation before implementation begins.

### **Human Resources (HR) and Industrial Relations (IR)**

Probably the greatest challenge is that the staff who work in the laboratory services of ten different employers (all the provinces excluding the Northern Cape which does not render any of its own laboratory services, the national Department of Health and the SAIMR) have to be transferred to the employment of a single new employer. There are an estimated 4 500 staff members involved. They are employed under two different sets of conditions of employment and under the provisions of different bargaining arrangements, those of the Public Service and those of the SAIMR.

There has therefore been a very heavy focus on human resources issues. Eight unions are involved in the NHLS and all eight are involved in the Interim Negotiation Forum (INF) that was required by the Cabinet decision to establish the NHLS. The first year was marked by a rejection by the unions of the “parastatal” as the vehicle for the NHLS and this resulted in a stalemate.

The INF was established to enable discussion of labour issues that will affect all of the prospective employees of the NHLS. The Cabinet required that this be done in the spirit of the National Framework Agreement for the Restructuring of Parastals (NFA).<sup>5</sup> The NFA is an agreement that the government, organised labour and organised business entered into in February 1996 for the orderly restructuring of state owned assets. While the focus was on the four large state owned enterprises, Telkom, Transnet, ESKOM and DENEL, the NFA specifies that the agreement includes the state assets of the Transkei, Venda, Bophuthatswana and Ciskei (TVBC) states.

Clearly the establishment of the NHLS involves the restructuring of the public sector laboratories. This will include the introduction of a single new job grading system, a new remuneration model and a set of common benefits for the NHLS. While the provisions of the Basic Conditions of Employment Act No. 75 of 1997 (BCEA) establishes the minimum requirements that are protected in law, there are “matters of mutual interest” that have to

be negotiated and agreed to by labour and the employer. The matters that have to be negotiated are prescribed in the Labour Relations Act No. 66 of 1995, as are matters that the employer must consult labour on and the mechanisms and procedures for reaching agreements. The NHLS does not presently exist as an employer so no permanent bargaining structure can be formed yet. The dilemma that the INF tried to overcome was that the Public Service Sectoral Bargaining Chamber (PSCBC) does not cater for the SAIMR staff and the SAIMR bargaining arrangements do not cater for Public Servants. The Project Team attempted to use the INF as a consensus-building forum. The idea was that the consensus would be 'banked' and only agreed to once the NHLS was established, at which time a valid bargaining structure would be implemented. To this end the Project Team tabled a "procedural agreement" for discussion, but the insistence of the unions that the NHLS should not be a parastatal resulted in the document, plus draft documents containing proposals on various conditions of service, never being discussed. The INF meetings were suspended for four months until NEHAWU met the Minister and then agreed that the public entity would be established. The INF met again on 5 July 2000 at which time it was agreed that the unions could arrange their own workshop to determine their collective position on labour participation in the way forward. This workshop finally took place on 4 and 5 October 2000. Subsequently on 17 October 2000 the unions demanded the disbanding of the INF and its replacement with structures detailed in the NFA.

During this time the Project Team continued with the detailed planning of HR issues. These included the process for the designation by the respective government departments of those employees who work in government department laboratories and who are therefore to be transferred to the NHLS, conditions of service, a grading system, remuneration policy, employment equity policy and several other labour issues. The unions and the project team were transmitting different messages to the staff and anxiety began to rise. The Project Team embarked on a "Roadshow", visiting all major centres and addressing mass meetings of staff, in an attempt to allay fears that had been expressed.

While it was always clear who the SAIMR employees are, it was not possible to identify the government department laboratory employees in all instances. In some provinces the organisational structure is such that the employees are only identifiable as part of a hospital staff establishment. It was therefore necessary to get the provincial Departments of Health to create new 'components' for laboratory services in their personnel systems (PERSAL). Since only these components will be abolished and their functions and resources transferred to the NHLS, the Bill provides for the 'designation' of the affected employees. This different provision for Public Servants was misinterpreted despite deliberate communication of the facts and created a lot of anxiety for the staff concerned. At the time of writing all separate laboratory components have been created with the exception of one province.

Related to this lack of clarity was the fact that the inability to identify the affected personnel meant that it was not possible to determine union affiliation with any degree of confidence. The ideal would have been to extract the details from stop orders to unions in the personnel systems. This is an issue because it has not yet been possible to determine proportional representation of the eight unions in the INF or any other process.

One major issue that caused heated debate in the development of the organisational structures, and in drafting job titles and descriptions, is the question of laboratory management. Most pathologists feel strongly that only a pathologist can be a laboratory manager while medical technologists and medical scientists feel that they too are capable. The *de facto* situation across the country is that laboratories are managed by a wide range of

professionals and the main criteria for success seems to be management skill and not any one professional background. Another issue that causes constant tension is that academics often hold different perspectives to those of other staff who run the services. The debate is complex and there are different issues at stake in each medical school and between disciplines of pathology. The impression is that the most important factor that influences successful laboratory service is the ability of a group of people to work together.

In any organisation there is a need to determine the relative value of each job to the organisation. This guides recruitment policies and lays the basis for a consistent remuneration policy. Job value is arranged and managed through a grading system. There are many systems available, some widely implemented in South Africa. The Project Team pursued the Hay Grading System because it offers an opportunity to separate the core professions (pathologist, medical scientist, medical technologist and medical technician) from the administrative support and management jobs of the organisation. The professionals can pursue chosen career paths in their professions by gaining in competence and making themselves indispensable to the organisation for technical reasons. This means that they do not have to pursue managerial positions as the only means of advancement (although of course they may still choose to become managers). The implementation of this dispensation will require some careful management if it is to bear fruit.

### **Quality Assurance, Research and Development**

In the early stages of consultation the Project Team promoted a model that would have seen the laboratories associated with university faculties fully incorporated in the NHLS. Several universities, however, were in favour of a model that would have taken all of these laboratories out of the NHLS and seen them run by the university faculties. This was not in keeping with the TTT report and the Cabinet decision to establish one national entity.

More recently a “hybrid model” proposes that the laboratories be inside the NHLS and a core staff who are responsible for the academic functions of teaching and research be employed by the university concerned. The details of the model rely on flexibility for the university to be able to generate revenue from clinical trials and other research-linked work. This will decrease their dependence on revenue from the NHLS services and enable the NHLS to offer services to the provincial administrations at tariffs that do not subsidise academic functions. The NHLS will however still have to support the universities, especially in the beginning, to ensure that there is proper provision of trained staff for the future. The issue of university faculties having to generate revenue and the prospect of not being guaranteed resources and funding by the NHLS for teaching and research have resulted in a fair measure of anxiety for the medical schools. Methods of securing transfer funding from the national Department of Health through the mechanisms of conditional grants are being explored.

Quality assurance and control have been hotly debated. As indicated the present laboratory quality country-wide ranges from very poor to world-class. The aim has been to build consensus on the content of a policy that will result in all laboratories participating in a quality control programme and, where appropriate, an accreditation programme. There are developments that will soon see all laboratories being required to obtain accreditation with the South African National Accreditation Standards (SANAS). The implications are not clear and the costs of this have not been spelt out yet. Meanwhile the ‘total quality management’ (TQM) programme that is envisaged is based on the standards of the International Standards Organisation (ISO), the relevant standards being ISO 25.

## Information Technology (IT)

Laboratory services essentially sell test results as their main product. The process requires that the specimen be taken to a laboratory that can do the test, in a form that preserves the element to be tested, that the specimen be tested and that the result be transmitted to the requesting clinician in an acceptable time period (and with confidence that it is accurate) in order to influence the clinical management of the patient.

IT is an integral part of every supporting process in laboratory services. This includes the laboratory system itself plus the HR, procurement, transport and billing systems that enable cost-effective and efficient management of laboratories.

There are a myriad of systems presently in use in the several administrations and organisations that will become a part of the NHLS. There is a process underway to set a vision for an integrated laboratory management information system and to determine how to make the most of the existing systems during the interim period. Step one will be to consolidate the capacity and optimise the current systems so that they can be rolled out to the parts of the NHLS that have no computerised systems. The second step will be the introduction of the totally integrated management system.

## Communication

A mass national meeting was convened on 8 June 1999 to initiate the NHLS process. On two occasions the Project Team also conducted 'Road Shows' where mass meetings of staff and stakeholders in eight main centres across the country were addressed and questions answered. Staff, managers, union representatives and other interested parties attended all of these meetings.

A full list of each and every stakeholder was compiled and each person has received a personal copy of a 'Transformation Survival Kit', to which is added fact sheets from time to time as the details unfold. These kits are essentially files that have been provided to each individual wherein they can file all NHLS correspondence and communication pamphlets during the transformation period. A helpdesk is provided with the assistance of co-ordinators in each province and each major institute. A 'Business Television Broadcast' was held on 1 December 1999. This is a closed circuit television broadcast to specific receivers. It was possible to use existing networks to about 50 sites around the country. In this way over 2 000 stakeholders were reached in the two hours available. The broadcast was from a studio in Johannesburg. Viewers were able to phone in to speak to a panel and many questions were posed and answered. All unanswered questions were answered in 'Fact Sheets' of the 'Transformation Survival Kit'. Several bi-lateral meetings were held with unions (notably NEHAWU, HOSPERSA and ISA). A website has been established by the Government Communication and Information Service (GCIS) and is regularly updated ([www.nhls.gov.za](http://www.nhls.gov.za)). All documentation relevant to the NHLS is on this site. So far most of the enquiries that have been received in connection with this site have been from international parties.

## Payment of the Transformation Process

The costs of all of the consultants except the Project Leader are paid for from funds set aside in the SAIMR and approved by the Director General of the national Department of Health. This money will also provide for changes such as signage and stationery when the NHLS commences and cash flow bridging finances in the initial months. What this means

is that when the NHLS commences the personnel that were previously paid by both the SAIMR and all of the government departments will have to be paid by the NHLS. However, the system will inherit the cash flow of only the SAIMR fee-for-services. It will have to wait until the end of the first month to invoice the government departments for services rendered. These departments could take two or three months to process the payments. This means that the NHLS will have to carry the cash flow of these costs for some time until the new cash flow stabilises. The money had been deposited in an account of a trust (SAIMR Foundation) established in 1995 to protect research funding. This money was from the reserves of the SAIMR, accumulated in the good financial times. The trust, which contained about R62m at the time, has been terminated and the funds are to be shared between research funding (through a new trust for the benefit of all eight university pathology departments), and the costs of the restructuring. Most of this money is set aside for the stabilisation of the cash flow.

### **SAIMR developments**

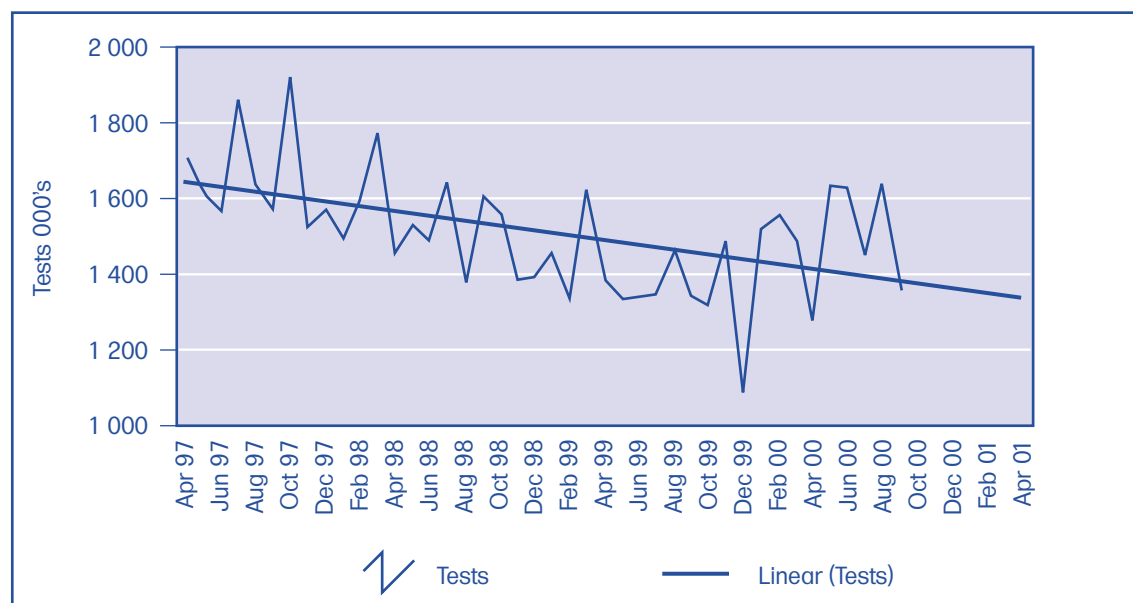
The developments at the SAIMR are critical to the establishment of the NHLS because it is the biggest of the services. Its systems are designed for a public entity and its staff are familiar with managing a public entity. Of serious concern therefore is the financial decline of the institute over the past few years. Table 1 shows the main figures from the annual reports of the SAIMR since 1997.<sup>4</sup> At the present trend the SAIMR cash reserve will be depleted in March 2001. This has been partly due to the poor payment record of the provincial administrations that account for 95% of SAIMR business. Payments have improved in the past six months but are still not optimal. The Institute has embarked on a strict payment management plan that will result in closure of laboratories if the payment schedules are not met.

Table 1: The South African Institute for Medical Research, Audited Group Balance Sheet History

	1996/97 R'000	1997/98 R'000	1998/99 R'000	1999/00 R'000
CAPITAL EMPLOYED				
SUBSCRIBED CAPITAL	332	332	332	332
DISTRIBUTABLE RESERVES	73 984	70 359	41 877	23 889
NON-DISTRIBUTABLE RESERVE	19 080	19 080	19 080	19 080
LONG TERM LIABILITIES	26 970	27 190	26 151	25 943
	<u>120 366</u>	<u>116 961</u>	<u>87 440</u>	<u>69 244</u>
EMPLOYMENT OF CAPITAL				
FIXED ASSETS	52 292	50 908	39 621	29 346
INVESTMENTS	35 370	23 198	8 453	3 553
NET CURRENT ASSETS	32 704	42 855	39 366	36 345
CURRENT ASSETS	<u>90 942</u>	<u>94 149</u>	<u>83 757</u>	<u>84 639</u>
Inventory	7 736	6 464	4 263	4 608
Accounts receivable	60 072	80 854	62 774	72 410
SAIMR Trust	1 260	-	901	-
Cash and bank	21 874	6 831	15 819	7 621
CURRENT LIABILITIES	<u>58 238</u>	<u>51 294</u>	<u>44 391</u>	<u>48 294</u>
Accounts payable	40 136	31 849	28 376	32 161
Provisions	18 102	16 276	16 015	16 133
SAIMR Trust	-	3 169	-	-
	<u>120 366</u>	<u>116 961</u>	<u>87 440</u>	<u>69 244</u>

The other major cause of the financial decline is a steady decrease in volumes of tests requested by clinicians (Figure 1). This has undoubtedly been as a result of the financial pressures that provincial departments of health experience themselves. The normal response would have been to downsize the labour-force. This was not done because of the pending NHLS. It was felt that it would be unwise to trim only part of the organisation prior to amalgamation with the public service components. The consequences of this approach were known and agreed to at the time that the Interim Board was appointed but the price has been high.

Figure 1: Volume analysis SAIMR 1997 - 2000



The Institute embarked on other measures to try to contain costs and to increase revenue. Top managerial position salaries were frozen, new posts were filled by contract employees rather than permanent employees and an evaluation has been done of the internal laboratory media and reagents manufacturing capacity and quality in the Institute. There has also been a process to evaluate the introduction of a single automated laboratory in Johannesburg General Hospital. The aim is to make routine tests available 24 hours a day from a single laboratory. This will reduce specimen collection and introduce better economies of scale. However, it means moving to a shift system instead of overtime and will result in a reduction of staff. There is also a risk that the remaining specialised laboratory capacity is compromised by the removal of equipment and other resources to the automated laboratory. If this happens the likely response will be a demand for additional (duplicated) equipment.

The Institute owns a company called South African Vaccine Producers (Pty) Ltd (SAVP). The production of vaccine has been economically non-viable for years. The Institute was trying to upgrade to a new more technologically advanced system but fell short of funds. The bulk of the work in 1999 was therefore a subcontract to Pasteur Merieux Connaught to combine and package various vaccines from imported bulk. The vaccine production capacity has been stopped and key staff were seconded to other scientific institutions (such as CSIR and NIV) pending government's decision on a joint venture vaccine manufacture initiative. The SAVP also manufactures and distributes anti-venom sera. There is a project underway to examine ways to make the anti-sera operation profitable.

An additional source of revenue for the SAIMR (and therefore the NHLS) is the private sector. The University of Pretoria won a tender to provide laboratory services to Transmed, a large national medical aid. The university trades under a company called Health Enterprises at University of Pretoria (HE at UP). This company entered into an agreement with the SAIMR to provide the services in the rest of the country outside of Pretoria. This contract has stretched the managerial capacity of the Institute but it will increase volumes of tests to a point that will make more laboratories independently viable. The reaction of the private pathology firms has been predictably very negative. Some of them are owned by the same companies that own some of the private hospital groups and there has been an attempt by

the hospitals concerned to prevent the HE at UP and SAIMR from providing the service. The SAIMR retains any profit that it makes from the services that it provides to Transmed in terms of this contract as does the HE at UP. However, the objective for SAIMR at this stage is not necessarily to make a “profit” but to increase volumes of tests to the under-utilised laboratories and so avoid increasing unit costs. It also means that several unprofitable laboratories can be sustained, and therefore services to the public service assured by ensuring sufficient volumes of work. For the university it means a source of revenue to pay for their contribution to academic pathology services (teaching and research). This is a very important development to monitor in the future. The potential exists for the NHLS to force pathology prices down in both the public and private sectors by dominating the market and providing a cheaper service that private health care providers choose above private pathology services. The government health services, including Pretoria Academic Hospital, will be obliged to purchase laboratory services from the NHLS and the NHLS will have to decide if it is most efficient and effective to contract HE at UP (or any other company) to provide services as a subcontractor.

The Faculty of Health Sciences at University of Witwatersrand is inextricably linked to the SAIMR which is the *de facto* School of Pathology of the university. The university has established a company called Wits Health Consortium (WHC) that has a section known as Contract Laboratory Services (CLS). The WHC and the SAIMR have entered into an agreement to contribute capacity from each of the partners to secure clinical trial work for their mutual benefit. There is an ongoing discussion about how to structure the relationship and the profit sharing of this arrangement.

## Other developments

### NIV BL4 Laboratory

South Africa has one of only two bio-level four laboratories in Africa. The other is in Egypt. Virtually all of Africa’s testing on African Haemorrhagic Fevers (Congo Fever, Lassa Fever, Marburg Fever, etc.) is done in this laboratory in Rietfontein. The laboratory is old and has reached a point where it will become dangerous soon. Technology has progressed and there are newer designs that will require the building of a totally new laboratory, rather than renovating the existing structure. Government will have to take a strategic decision on whether to continue to provide such services in the future. If the decision is to do so then a new laboratory will have to be constructed. These laboratories cost about R50m or more.

### New Durban Laboratory

The new academic hospitals in Durban and Umtata have both been provided with modern laboratories. These offer excellent opportunities for developing integrated laboratory services from the outset in these two major centres.

### New Head Office Premises for NHLS

The NHLS needs to have its own identity. The SAIMR owns a large complex of buildings at Rietfontein, most of which is not utilised. A process has been embarked upon to renovate a part of the complex for the Head Office of the NHLS. It is a very accessible site, safe environment and offers opportunities for expansion.

## Other

The NHLS will include all public laboratory services, including human genetics, occupational health, forensic pathology, entomology and some food and water testing. It will also manage the National Cancer Register (NCR). The provision of these services is relatively complex and fragmented. Each is being managed separately. There is still some discussion between the Department of Health and the Department of Labour regarding occupational health laboratory services, and between the Department of Health and the Department of Safety and Security concerning forensic services. Water and food testing is still very fragmented. Some of the more complex food laboratory testing is done in the forensic chemistry laboratories. Rationalisation of these services needs to be attended separately in the future. Some entomology services will be integrated into the new NICD but it may be necessary to review the arrangement in this respect with the Medical Research Council in due course.

## Next steps

Once the NHLS Bill is enacted, and commencement dates have been promulgated, the provisions can be implemented. This is a fairly complex process and there are several options for the sequence of events to follow in 2001.

### Transfer to the NHLS (S197 and S189)

Essentially what is to happen is the transfer of “businesses” from the current ten employers to a totally new employer.

The main legal provisions are in terms of sections 189 and 197 of the Labour Relations Act, No. 66 of 1995. There are eight provincial administrations, the national Department of Health and the SAIMR who are current employers. Technically there are only two employers (SAIMR and the Department of Public Service and Administration) but in practise there are ten. Section 197 provides for the transfer of a “going concern”, in which case the employees will be transferred with their current remuneration and conditions of service to the new employer. Section 189 provides for the restructuring of a business due to operational needs.

The problems of transferring employees from ten employers at the same time are enormous. It will be tempting to minimise the problems by taking employees on their current conditions of service. However, these conditions are very different and very soon employees who perform the same jobs will be very unhappy about being rewarded in different ways. So, even if the section 197 route is followed it will be necessary to embark on a section 189 restructuring exercise soon anyway. The option is to start with the section 189 restructuring as the tool for establishing the new entity. There are risks and complications. Firstly, there has to be a bargaining and consultation mechanism in place and this cannot be put in place until the NHLS is a ‘juristic person’ (with a Board and management to represent the organisation). Secondly, the risk is that personnel are disenfranchised by the changes in conditions, notwithstanding the fact that the law requires that conditions may be no worse than prior to the restructuring. Thirdly, personnel have to understand the new remuneration policy and conditions and it will be a long time before everyone understands them sufficiently to make the transition. Finally, where there are matters of ‘mutual concern’ the new conditions have to be negotiated between the employer and the unions. This can be a very lengthy process.

## Provincial Preparation

At the same time that decisions are being taken on the route to follow for the establishment of the NHLS the present employers must prepare for the transfer of the function. In the case of the SAIMR this is relatively straightforward. All employees, all assets and all goods, services and contracts will be transferred. In the case of the government departments it is infinitely more complex. As has been described, in most cases the employees were part of sub-components of hospitals in the PERSAL personnel system. Staff who are part of the laboratory services are still not automatically identifiable. Each person has to be 'designated' as a part of laboratory services. The posts that these staff occupy are being moved to new, separate components for laboratory services in the PERSAL system. This will make the transfer of their records and conditions easier when the time comes.

The government departments also have to reorganise their budgets. At present they budget for salaries, administrative costs, equipment, 'stores and livestock', etc. Once the NHLS is the service provider they will purchase the services from this third party. This requires that the funds have to be reallocated to 'Professional and Specialised Services' in the budgets. The funds that provincial departments use to pay for the laboratory services are, in some cases, in different programmes and sub-programmes in their budgets (ie, not all clearly identifiable as 'laboratory services'). It is therefore not possible to simply 'ring-fence' an existing amount and change its description in the budget to reflect the fact that laboratory services will be purchased in future from the NHLS. This increases the amount of work that has to be done in preparation for the NHLS. There are cases where parts of the money that is budgeted for laboratory services are in totally different government departments, such as the Department of Public Works.

It may be advisable to transfer the services from one or two administrations at a time and therefore to stagger the commencement dates.

These are a few of the many administrative issues that have to be managed. Photocopiers may be on hospital stock but be 'laboratory property', lease contracts for equipment and premises have to be transferred, etc. This will take many months to finalise and depends on the decisions regarding commencement schedules and the labour relations route to be taken.

## Lessons and recommendations

There are lessons to be learnt generally regarding transformation of government functions and services into a public entity and there are specific lessons and opportunities related to the laboratory services.

### Transformation lessons:

1. It is clear that the establishment of a new public entity is an enormous job and requires dedicated resources (people and money). This cannot be done as a part-time job of officials in the Department of Health.
2. The preparation and piloting of legislation for such an entity takes time and requires very wide consultation.
3. The labour issues are complex, time-consuming and require specialist legal advice.
4. Historical prejudice and entrenched personal agendas are far more prevalent and powerful than first meets the eye.

5. No matter how much communication there is during a transformation process it is not enough. People hear what they want to hear and what they think that they have heard from perspectives prejudiced by their personal comfort with the perceived vision.
6. The establishment of a new public entity requires a large dedicated “cash float”.
7. Restructuring implies integration of functions and amalgamation of components. This causes suspicion, anxiety and fear of change. There is a need for a separate Change Management process over and above the technicalities of Project Implementation.

#### **Lessons and opportunities for Laboratory Services:**

1. Great care has to be taken to preserve an appropriate, acceptable and affordable balance between the ‘academic functions’ and the services.
2. The viability of laboratory services is extraordinarily volume sensitive and the purchasers have to be aware that prices (tariffs) are linked to the volumes of tests that they request. Cross-subsidisation of services is absolutely essential if stable services are to be provided as a public health imperative.
3. There are ways to improve and/or stabilise volumes. One way is to capture additional market share but this is essentially from the private sector. This means that service levels must be competitive and that a backlash must be expected from the private competitors (many of these competitors own shares in private hospitals and can sabotage entry into this market).
4. Another way to improve viability is to reduce the unit costs. The most dramatic way to do this is to automate tests. This has service organisation implications and raises labour relations issues.
5. A public entity does not have the private sector competitor motivation to demand quality and higher levels of service. Quality assurance and Total Quality Management have to be driven by other forces. The main force that will determine quality is likely to be academic and professional pride. This has to be nurtured. Mandatory accreditation is not likely to be the solution but voluntary and progressive accreditation with appropriate reward systems may well achieve the goals.

The implementation of the NHLS has not yet commenced. It will be interesting and important to follow the process in 2001.

