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NATIONAL HEALTH LABORATORY SERVICES IN KENYA: CHALLENGES FOR THE NEW MILLENNIUM

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P. J. OJWANG

I want to begin by expressing my gratitude to the Kenya Association of Clinical Pathologists for inviting me to this meeting and for making it possible for me to share this momentous occasion with friends and colleagues whom I have not seen for a long time. I am also particularly happy to be back at this institution and in the very auditorium where the inaugural conference of the Kenya Association of Clinical Pathologists was held seven years ago.

By way of introduction to my presentation, I want to emphasise that I feel particularly honoured to have been invited to deliver this second lecture in memory of our late brother and friend, Professor Edward George Kasili. This Memorial Lecture is indeed a fitting tribute to a man who was a national and international giant in the practice of pathology. Professor Edward Kasili, or simply Edward as I always called him, was a national and international giant in the practice of pathology. The late Kasili was a man of vision, great simplicity, integrity and honesty. He was a dedicated family man, a true loving husband to his wife Esperansa and a generous and caring father to his children. To his friends, he was always engaging, congenial and affable; to his students, he exuded intellectual strength and excellence and to his professional colleagues he was a true and committed academic. The first thing that many of you would want to know is why I chose this particular topic for my presentation today. The first reason is my recollections of the numerous discussions we had with Professor Kasili regarding the state of pathology services in this country. I remember discussing with him the appropriate direction we wanted defined for our discipline in the delivery of health care. That was our last encounter in August 1994 and I can still remember clearly the pessimism he expressed regarding the state of his own health as we parted.

The second reason for choosing this topic pertains to the central role played by pathology in health care management. For this particular reason, it is critical that we, as members of the profession, establish right to shape our own destiny in matters that relate to the growth and development of our profession. We must be at the forefront in the formulation of policies that will guide us into the next millennium.

At a personal level, the topic provides me with a rare and unique opportunity to communicate my own random thoughts regarding some of the challenges which I believe will face us in this country in the practice of our profession as we strive to deliver laboratory services to the people of Kenya in the new millennium.

I want to begin by defining our role as pathologists and scientists and in doing so, let us examine the scope of our activities and professional responsibilities in the health service. At the core, is the provision of consultant and diagnostic services, in anatomic pathology, forensic medicine, haematology, chemical pathology, medical microbiology immunopathology and in many other subspecialties of pathology that have developed in recent years. The purpose is to assist our clinical colleagues in the diagnosis, management and prevention of diseases. It is in this area of our activity that we interact very closely with our clinical colleagues in the delivery of health care.

In providing diagnostic services we work together with our technical colleagues and use a wide range of sophisticated equipment and reagents. Other equally important functions of pathologists include, disease surveillance epidemiology, infection monitoring, antibiotic policy formulation, postmortems- both routine and forensic, medical audit, service-related research and staff training and development.

At this point, I would like to mention one specific role that has hitherto not been particularly appreciated and which is becoming a dominant activity in the daily working life of some of our colleagues. I am referring here to direct clinical care of patients which in some disciplines, is becoming a distinct role of pathologists. For example, as chemical pathologists we have expertise in our understanding of the biochemical basis of disease and the metabolic processes that occur in the body. We are therefore equipped to provide clinical care to patients with endocrine and metabolic problems. We have a distinct role to play in the clinical management of patients with disturbances of acid-base, electrolyte and fluid balance, diabetes mellitus, hyperlipidaemias and a variety of endocrine disorders.

The haematologists now have a dominant role in the clinical care and management of patients with oncological disorders such as lymphomas, leukaemias and multiple myeloma and in haemorrhagic syndromes such as thrombocytopaenias and haemophilia. Immunopathologists now look after patients with allergic disorders, and the management of patients with bacterial, viral and parasitic infections is now the responsibility of some of our colleagues in medical microbiology, virology and parasitology, respectively. I believe we now also have anatomic pathologists looking after patients in the wards.

CONCERNS

I now want to turn my attention to some of the major concerns relating to the provision of diagnostic laboratory services in the public sector and some of the challenges facing the practice of pathology in the new millennium. In Kenya as in many other parts of the world, the major concerns in the provision of National Health Laboratory Services relate, first of all, to an ever increasing workload accompanied by the diversity and complexity of tests that need to be performed. In many instances we as professionals have been the cause of this increased demand through the improvement in our capacity and competence to process heavy loads. This is well illustrated in the case of Chemical Pathology where the use of multichannel, high throughput analysers give us the capacity to analyse a large number of samples within a short period of time.

The other major concern is the rapid rate at which the available resources are diminishing. This is particularly true in a country like ours where, because of the poorly performing economy, the budget allocations have to be trimmed and our experience is that pathology services are always the first in line to feel the impact of these restricted budgets. The challenge therefore is constantly upon us to work within the limits of the allocated budgets, which inevitably produces a lot of strain in the provision of efficient and quality laboratory services in public institutions. It is therefore critical that we develop strategies to address these issues.

ORGANISATIONAL STRUCTURE

We have a National Pathology Service Management structure which has been in existence for more than three decades now. The service is still administratively an integral part of the National Health Service system of this country, drawing its operational budget directly from the Ministry of Health. The Administrative Head of the NHPS is the Director of Laboratories who is normally a doctor, but not necessarily a pathologist. He is responsible to two bosses—namely, the Permanent Secretary and the Director of Medical Services. The Director, NPHL is assisted by the Chief Medical Technologist and his deputy who together have responsibility for the heads of the provincial and district laboratories. The heads of the Division of Vector Borne Diseases and Vaccine Preparation Unit are accountable to the Director, NPHL. Whilst this structure served us well in the past, there are indications that it is not compatible with the present demands of National Health Laboratory Services. I am at this point suggesting that serious consideration must be given to the need for complete reform of the National Health Laboratory Service both in its structure and operations.

I believe it is not inappropriate that I should propose that the NHLS becomes an autonomous body—a government owned corporate entity created by an Act of Parliament. The primary objective of this new entity will be the provision of pathology services to the public sector.

This parastatal will have to work on strict business principles and levy fees for the services it renders. Whilst it may have the preferred provider status initially, it must gear itself to future competition from the private sector. I am further proposing that consideration must be given to the complete privatisation of this entity in the near future.

For the present, it is envisaged that the proposed new entity should be headed by the Chief Executive accountable to a Board. The Board will be appointed by the Minister for Health, and will include the Permanent Secretary, Ministry of Health and the Director of Medical Services as well as representation from all the stakeholders including the users. All policy issues will be determined by the Board, within the provisions of the Act and guidance by the Ministry of Health. Services will be provided through a system of Provincial branch offices which will set up a system of laboratories in each province.

I am proposing a complete paradigm shift in the operations of the new entity. It must be the aim to be a self-sufficient organisation in which accountability and productivity will be the key yard-sticks in determining overall performance of all personnel. Service operations and individual officers will have to be subjected to periodic audits and consideration must be given to the introduction of performance contracts rather than open-ended tenures.

QUALITY, CLINICAL AUDIT AND ACCREDITATION

As laboratory experts, the question of quality is always central in our mind, especially in the present environment of evidence-based laboratory medicine. We now recognise that quality goes beyond mere production of accurate results or the production of acceptable statistics on analytical imprecision. These have been addressed by the introduction of internal and external quality assessment schemes. However, there is now need to control complete laboratory process activities—pre-analytical, and post-analytical—through Total Quality Management Systems. Total Quality Management Systems must be subjected to clinical audits to ensure conformity with agreed standard; that objectives as defined in the Quality Systems are being fulfilled; and that all staff are carrying out their assigned duties and responsibilities.

As a natural sequel to Total Quality Management, there is peer recognition and national or international certification or accreditation. There are existing international standards of certification like the ISO 9001 and those for accreditation such as the ISO Guide 25. Independent agencies undertake accreditation schemes such as the CPA (UK); CCK-test (Netherlands), and NCCL (USA). Accreditation by these international agencies provides a stamp of approval with regard to proficiency and competence.

It is an indictment on the part of our clinical colleagues in the public health institutions to continue to accept laboratory results which have not been subjected to rigorous quality checks. There is no guarantee that in the private sector things are any better with regard to quality. And

what are we doing in Kenya with regard to laboratory accreditation? I know we have the professional expertise to carry the process through, but do we have the material and financial resources required? Is the Ministry of Health prepared to commit itself to this challenge? Several international pharmaceutical companies are now moving into Africa to undertake clinical drug trials but associated tests will be done only in those laboratories that have internationally recognised accreditation.

I would like to propose at this stage that we must consider the need for a clear and unambiguous defining Act of Parliament which will regulate the performance of all clinical laboratory testing in Kenya and which will underline the required standards for proficiency and competence and those pertaining to certification and accreditation. The Act will also redefine what a clinical laboratory is and what practices fit into this definition. It will give clarity to the standards that apply to the qualifications of laboratory personnel, quality control and quality assurance. It is however important that clinical laboratories are not over-burdened with regulations.

STAFF TRAINING AND DEVELOPMENT

The provision of efficient and quality laboratory services requires a critical mass of trained, well motivated staff of all cadres: pathologists, scientists and technologists. The shortage of pathologists in this country was to be addressed by the establishment of the Master of Medicine (M Med) postgraduate training programme in pathology of the University of Nairobi in the mid-eighties. The aim was to see pathologists in charge of laboratory services in the provincial and district hospitals before the turn of the century. We can say confidently that we are nowhere near achieving this target and the acute shortage of pathologists will continue into the next millennium. I understand that for the last two years we have not had any students admitted into the programme.

Perhaps we should now be asking ourselves whether we have the right training programme in place and why it does not appear to be attracting potential candidates. Have we ever undertaken an audit of the present multi-specialty training programme? Would it be appropriate if we converted to a mono-specialty programme or if we made provisions for a mixture of the two approaches? And should we continue to have the University of Nairobi as the only certification agency for competence in the alternative training and certification agency? Indeed, why should the Kenya Association of Clinical Pathologists not have a direct role to play here?

I have asked many questions and I must admit that I do not seem to have any specific answers to most of them. My point is to raise them as issues for debate and challenges to be addressed as we enter into the new millennium. Currently, we also have problems of retention of pathologists in the public sector and at the moment, the country has lost some of its most senior pathologists to the private sector. As a country, we should not shy away from

discussing the issues that have led to this state of affairs. It is critical that targeted retention strategies are adopted that go beyond the mere improvement of the remuneration packages and terms and conditions of service. Public/private sector partnership involving shared expertise and resources must also be considered.

Staff development must include non-professional laboratory personnel such as health management specialists, systems analysts and computer hardware and software technicians. Within the established framework, there must be set policies that shape the pattern and direction of staff development in National Health Laboratory Services to meet the challenges and demands of the new millennium.

INFRASTRUCTURE AND EQUIPMENT

The environment in which the staff work and the equipment with which they perform their allocated duties make a major contribution to their well-being. Concerns have been raised about the deteriorating physical infrastructure in our health institutions, including laboratories. Facilities for staff as well as patients, desperately need maintenance in some laboratories and we have to continually ask ourselves whether the infrastructure is still appropriate for the services offered and for the proper functioning of equipment. I have already alluded to the need to maintain high standards of quality but this must be directly linked to the availability of appropriate instrumentation. It must be an impossible challenge to attempt to produce results of good quality if you do not have appropriate instruments which are functioning optimally.

In order for a laboratory to continue to have appropriate equipment, it is necessary to have a management procedure which involves a continuing assessment of need and mechanisms for evaluation and purchase. A formidable challenge for the new millennium, is therefore, to modernise equipment in our laboratories, mortuaries, post-mortem rooms and blood-banks. We must have the will to keep pace with modern technology and to maintain all existing equipment in our laboratories. The other key area that needs major attention with regard to equipment is laboratory information systems. All the sophisticated analysers are now controlled by computers. The vast amount of data handled and processed in our laboratories cannot be done manually. Computers are now an essential tool for data capturing, processing, reporting and electronic storage. With appropriate software capacity, they are also extensively used in the creation of management schedules and programmes for costing and financial administration.

It is abundantly clear that in the 21st century, efficient and cost-effective management of our laboratory services cannot be undertaken without an appropriate information system involving the use of computers. We have to decide whether we want to move with the rest of the world into the digital age of the new millennium.

HEALTH AND SAFETY

As laboratory personnel, we are constantly exposed to a variety of infectious agents as we handle human samples in our daily work. The present HIV/AIDS epidemic has heightened the potential for infection. Whilst the responsibility for the organisation and management of health and safety lies with the NHLS management, the successful implementation and maintenance of health and safety policy depends on the co-operation of all personnel in the laboratory.

It must be a legal requirement that the National Health Laboratory Services Management prepares and, as often as may be appropriate, revises a written statement of the general policy with respect to the health and safety at work for employees and any other person entering the workplace and of the organisation and arrangements for carrying out that policy. Individual laboratory management teams will then have the ultimate responsibility to ensure that health and safety policy is implemented. I do not have the statistics, but it is not inconceivable that several laboratory personnel have acquired fatal infections as a result of exposure to potentially infectious samples in our laboratories. Emphasis on health and safety at work therefore requires a higher degree of impetus.

RESEARCH AND NEW TECHNOLOGY

We are all aware of the phenomenal technological advances that have taken place in the field of laboratory medicine during this century. We have seen spectacular developments in method techniques and instrumentation in all branches of pathology. In my own speciality of Chemical Pathology we have seen the evolution from the purely isotopic immunoassay methods to those that incorporate immuno-assay with enzyme-linked

measurement systems involving spectrophotometry, chemiluminescence, fluorometry and phosphorescence.

The one new field that seems ready to find application in all branches of pathology is molecular biology or biotechnology. The sophisticated techniques in molecular biology such as polymerase chain reaction (PCR) have received extensive applications in disease surveillance and diagnosis. In Chemical Pathology, we now routinely apply these techniques in the diagnosis of inborn errors of metabolism and other genetic disorders. PCR has the advantage of sensitivity and specificity offer flexibility and a faster turn-around time.

Presently, these molecular techniques may be regarded as blue chip technology in a country such as Kenya but there is no doubt at all that this is the technology of the twenty first century with abundant potential in laboratory diagnosis and research, for all disciplines in laboratory medicine.

As a country, we shall therefore have to decide on the magnitude of investment we need to make in the development and application of molecular technology if we are to avoid the risk of being excluded from an important segment of the real world of the science and practice of medicine in the new millennium. We cannot afford to ignore research even as a service-oriented body. Opportunities exist in carrying out operational research whose data may make significant contribution in the operation and management of the NHLS.

CONCLUSION

The National Health Laboratory Service is faced with a myriad of challenges in the new millennium. I have given my own random thoughts as to what some of these challenges will be. I must add that however formidable they appear to be, they will be conquered with the appropriate intervention strategies and determination.