

MANAGED EQUIPMENT SERVICES (MES) - HEALTHCARE FOR SUSTAINABLE DEVELOPMENT

The Kenya MES Experience

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1.0 Introduction

A healthy, productive work force is one of the ingredients for economic development. Health is therefore not only an inalienable human right, but it is also essential to economic growth, and is in turn crucial for sustainable development. This has been recognized by the Sustainable Development Goals ("SDGs"), which list health as one of the social needs that go hand in hand with ending poverty.¹ It is however, no longer feasible for any country, rich or poor, to provide its entire population with all the needed health services.² While both developed and developing countries face various challenges in the provision of healthcare, developing countries largely lack the resources, adequate legal framework and capacity to fully exploit the available interventions in ensuring good quality, effective, efficient and affordable healthcare. Further, the healthcare industry is constantly changing due to various factors including technological advances, policy adjustments, changing disease patterns and increased cost of healthcare, thereby making it difficult for developing countries to keep up with the healthcare requirements of the citizens. This leads to instances where people in developing countries suffer and lives are lost from conditions for which there exist effective interventions. In order to ensure sustainable development therefore, there is need to develop innovative healthcare financing strategies to address the challenges faced in the provision of healthcare services, particularly in developing countries.

The managed equipment services ("MES") arrangement is one such innovative financing strategy and this paper highlights the possibilities that it offers in promoting improved healthcare for sustainable development, as well as the possible challenges that may be faced, particularly by developing countries, when implementing such arrangements.

This paper focuses on the Kenyan experience in implementing MES for the provision, management and servicing of medical equipment in public hospitals across the country. The paper concludes by identifying possible areas of interest for UNCITRAL in providing guidance to facilitate implementation of such projects particularly in developing countries.

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¹ See Goal 3 of the Sustainable Development Goals adopted by the United Nations on 25 September 2015 as part of a new sustainable development agenda - available at <http://www.un.org/sustainabledevelopment/health/> <last accessed on 10 March 2017>

² Marc Mitchell, M.D, M.S, Harvard School of Public Health, 'An Overview of Public Private Partnerships in Health', p. 24 available at <https://www.hsph.harvard.edu/ihs/publications/pdf/PPP-final-MDM.pdf> <last accessed on 10 March 2017>

1.1 The Private Sector and Healthcare Financing Strategies

The SDGs have rightly recognized the need to encourage and promote partnerships for a successful sustainable development agenda.³ Accordingly, the private sector has an important role to play in closing the healthcare gap, as governments and other public agencies are increasingly leveraging on the financial resources, innovation, as well as technical and management expertise of the private sector in the provision of healthcare services.

In this regard, the managed equipment services arrangement is a business model that is currently emerging in the healthcare system, involving partnerships between the private sector and public healthcare providers, which offers a solution to some of the challenges posed by the dynamic healthcare industry as further elaborated below.

2.0 The Managed Equipment Services ("MES") Model

2.1 What is MES?

MES arrangements involve a long-term solution that is designed to provide health facilities with sustainable access to health infrastructure at a pre-agreed fee. It offers possibilities for promoting improved healthcare for sustainable development, by ensuring that public hospitals have access to modern health infrastructure, equipment and/or services over an agreed period of time, with the government making regular payments based on agreed performance parameters. Instead of the huge capital outlays that would otherwise be required for instance in building or equipping hospitals, MES arrangements offer public entities an opportunity to spread the cost over the contract period, thereby allowing for sustainable budgeting over long periods of time.

The features of MES arrangements can be tailored to suit the needs of a specific region or health facility, and can involve provision of physical infrastructure, delivery of equipment, installation, service, maintenance, provision of clinical services, training of existing healthcare personnel, procurement, consulting e.t.c. While MES arrangements are ideally suited to the needs of both developed and developing countries by providing an innovative financing structure to address the specific challenges they face in the provision of healthcare services, developing countries may however face challenges in implementing MES arrangements due to inadequate legal framework, and lack of capacity to undertake, implement and supervise such programmes.

3.0 The Kenya MES Experience

3.1 Kenya Country Profile

Kenya is an East African country with an estimated population of 43 million, according to the Kenya National Bureau of Statistics⁴. Over the years, Kenya has progressively continued to make structural and economic reforms that have contributed towards sustained growth. As the business hub of East Africa, Kenya has been highlighted in the World Bank's Doing Business

³ See Goal 17 of the Sustainable Development Goals

⁴ Kenya National Bureau of Statistics, '*Kenya Facts and Figures, 2015*' p. 1

Report, 2017 as one of the economies making the biggest improvements in its business regulations. In addition, Kenya has over the years taken important steps to improve the socio-economic status of its citizens, including health. According to Kenya's Health Policy, the government aims to attain the highest possible standard of health in a manner that is responsive to the needs of the people, through provision of equitable, affordable and quality health and related services at the highest attainable standards. One of the ways through which Kenya plans on achieving its health goals is by involving the private sector in health services provision and finance.

3.2 Legal and Regulatory Framework Governing Healthcare in Kenya

The Constitution of Kenya, 2010 ("Constitution") is the supreme law of the land and it contains a progressive Bill of Rights, including the right to health. It provides that *'every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care.'*⁵

Kenya has a devolved system of government comprising of two levels of government – the National Government and County Governments - there are 47 County Governments in Kenya. The Constitution allocates various public functions to either the National Government or the County Governments. With regard to the health function, the National Government has been tasked with responsibility over national referral health facilities and policy formulation over health matters in general. The County Governments on the other hand are responsible for all other health facilities other than national referral health facilities, and are also responsible for implementation of the national health policy at the county level.

There are various policy documents, which seek to implement the right to health as provided for under the Constitution. Kenya's development blue print, known as the Vision 2030 – which sets out the country's approach towards attaining upper middle-income status and improving the lives of Kenyans in general⁶ - identifies health as one of the key social sectors upon which the country's journey towards prosperity is based. The Vision 2030 is implemented through five year medium term plans which set out the planned policies, programmes and projects for the period covered. The Second Medium Term Plan which covers the period 2013 to 2017 recognizes that an efficient, motivated and healthy human resource base is pivotal for enhanced national competitiveness, economic growth and development.⁷

There is also a National Health Policy for the period 2012 – 2030, which focuses on health as a contributor to economic development as envisioned in the Vision 2030 and the realization of the right to health as enshrined in the country's Constitution.

While Kenya does not yet have overarching legislation on health, there is a draft Health Bill that is at an advanced stage in parliament and is expected to come into effect in 2017. Once enacted the Health Bill will provide a framework for, *inter alia*, a national health system encompassing public and private institutions and providers of health services at the national and county levels

⁵ The Constitution of Kenya, 2010 Article 43 (1) (a)

⁶ Government of the Republic of Kenya, 'Kenya Vision 2030', 2007 available at <http://www.vision2030.go.ke/> <last accessed on 10 March 2017>

⁷ Government of the Republic of Kenya, 'Kenya Vision 2030 Second Medium Term Plan (2013-2017)' available at <http://www.vision2030.go.ke/> <last accessed on 10 March 2017>

and facilitating in a progressive and equitable manner, the highest attainable standard of health services. Other highlights of the Health Bill include: i) recognizing the role of public private partnerships in deepening health service provision; ii) creation of a single regulatory body for health products and health technologies; and iii) providing a framework for healthcare financing strategies.

3.3 What makes Kenya MES Special

According to the Strategic Investment Plan for Kenya's Ministry of Health for the period 2014 to 2018, one of the goals towards building a progressive, responsive and sustainable health care system is to strengthen collaboration with the private sector.⁸ In this regard, Kenya is arguably the first country, not only in Africa but possibly globally, to enter into one of the largest sustainable healthcare projects through the MES arrangement involving the provision, management and servicing of state of the art medical equipment in approximately ninety-eight (98) hospitals throughout the country, at an estimated cost of United States Dollars Five Hundred Million.⁹ The implementation of the MES Project in Kenya was the first time such a structure was being used in Africa to equip health facilities.

According to the World Bank, Kenya has the potential to be one of Africa's great success stories from its growing youthful population, a dynamic private sector, a new constitution, and its pivotal role in East Africa.¹⁰ The World Bank also acknowledges that Kenya's interventions and increased spending on healthcare is paying dividends.¹¹

3.4 Inception of the MES Project

As stated above, the Constitution of Kenya allocates various health functions to the National Government and the County Governments respectively. In order to ensure harmony and coordination in the initiatives of both levels of government with respect to the delivery of effective healthcare to Kenyans there is a Health Sector Intergovernmental Consultative Forum which is made up of representatives from both levels of Government, and which meets regularly to discuss issues of mutual interest regarding healthcare. In October 2013, the Health Sector Intergovernmental Consultative Forum met and agreed on a proposal to equip public hospitals with modern equipment through the MES model.¹² The two levels of government therefore embarked on a comprehensive programme to upgrade 98 hospitals across the country with a view to improving access to specialized services countrywide by equipping the hospitals with critical equipment and human resource capacity building.¹³

⁸ Republic of Kenya, Ministry of Health, 'Ministerial Strategic and Investment Plan: July 2014-June 2018' p. 19 available at <http://www.health.go.ke/wp-content/uploads/2016/03/MINISTERIAL-STRATEGIC-INVESTMENT-PLAN.pdf> <last accessed on 10 March 2017>

⁹ The MES arrangement implements the Ministerial Strategic and Investment Plan, *op cit*, which lists various interventions to improve healthcare, including equipping of public hospitals, digitization of health facilities, systematic training of users of medical equipment devices and instituting a preventive and corrective medical equipment maintenance and repair system.

¹⁰ See the World Bank's Kenya Country Overview available at <http://www.worldbank.org/en/country/kenya/overview> <last accessed on 10 March 2017>

¹¹ World Bank Kenya Country Overview, *op cit*

¹² Government of the Republic of Kenya, 'Health Sector Intergovernmental Consultative Forum, A Summary of Discussions, 27-28 October 2014', p. 15 available at http://www.healthpolicyproject.com/pubs/782_HealthSectorInterGovernmentalCosultaALNov.pdf <last accessed on 10 March 2017>

¹³ Government of the Republic of Kenya, *Health Sector Working Group Report, Medium Term Expenditure Framework for the Period 2017-2018 to 2019-2020*, September 2016, p. 26

The proposal as approved by the Health Sector Intergovernmental Consultative Forum included the following: i) there would be three key partners under the MES arrangement, namely the National Government, County Governments and the private contractors; ii) the MES arrangement would cover contracts, running for an initial period of seven years with an option of renewal for an additional three years; iii) the private contractors would assume the risk and responsibility of procuring, installing, maintaining, and replacing the equipment in selected hospitals; and iv) the type of equipment to be procured would include theatre equipment, theatre CSSD equipment, renal equipment, ICU equipment and radiology equipment.¹⁴ Further, it was agreed that the private party MES contractors would be responsible for replacing the equipment on expiry of their lifespan as well as provide training to the staff that would be handling the equipment in the hospitals.¹⁵

3.5 Procurement and Selection of the MES Contractors

The tender for the supply, installation, testing, maintenance and replacement of medical equipment and associated training for all the health facilities through the MES arrangement was issued by the Ministry of Health in July 2014 as one international open tender. Some of the key features of the tender were as follows:

3.5.1 Number of Health Facilities: as stated above, the MES programme covers approximately ninety eight (98) health facilities comprising of two health facilities in each of the 47 Counties as well as four health facilities under the management of the National Government.

3.5.2 Bidding in Lots: the equipment to be supplied under the MES arrangement was divided into “Lots”, with each Lot containing a specific category of equipment to be supplied e.g. there were separate Lots for Radiology equipment, ICU equipment, theatre equipment, renal equipment etc., and each bidder was allowed to bid for more than one Lot. For each Lot, the contractors would supply, install, test and commission the equipment as well as carry out maintenance, repair, technological upgrades and replacement of equipment for the duration of the contract at a pre- agreed fee to be paid at regular intervals.

3.5.3 Original Equipment Manufacturers (OEMs): the tender was restricted to OEMs. The government’s intention in restricting the tender to OEMs was likely aimed at providing Kenyans with state of the art, modern medical equipment with regular technological updates, as well as cutting the costs of middlemen. The tender attracted OEMs from all over the world, and five internationally renowned bidders emerged successful.

3.5.4 Training: the services to be provided as part of the MES arrangement included on the job user and maintenance training, specialized training as well as clinical training in some specified fields.

3.5.5 Duration of the MES contract: the contracts were for a period of seven years, renewable for an additional three years, thereby totaling to a maximum of ten years.

¹⁴ Government of the Republic of Kenya, ‘*Health Sector Intergovernmental Consultative Forum, A Summary of Discussions, 27-28 October 2014*’, *Opcit* p. 17

¹⁵ *Opcit*

3.6 Lessons Learnt

3.6.1 Legal and Regulatory Framework

As is required for the success of any major public project, the importance of clear and effective procurement processes with clear roles and responsibilities must be underscored. Kenya has fairly robust procurement laws, which were useful in ensuring a smooth procurement process of the MES Contractors. Gains arising from a project financed healthcare project can only be maximized and healthcare improved with clear and effective processes. In addition to a clear procurement framework, clarity on the framework governing the provision of healthcare, addressing issues such as safety, quality of care and regulation of the healthcare industry in general is also important.

Kenya does not have adequate laws and regulations governing issues such as access to high quality medical equipment, appropriate use and disposal thereof. While there is a public procurement manual for the health sector which was issued in 2008 in recognition of the fact that the health sector has specific procurement requirements which may not be adequately addressed in the general procurement laws¹⁶, this manual is outdated as it was based on the now repealed Public Procurement and Disposal Act of 2005, which has since been replaced by the Public Procurement and Asset Disposal Act of 2015. Further, the manual does not recognize the emerging healthcare financing strategies. In this regard, one of the strategies that the Kenya Health Policy (2012 – 2030) seeks to employ to ensure adequate and appropriate health infrastructure (which includes medical equipment) is development of guidelines for the purchase of medical equipment and the disposal of the same. In addition, the draft Health Bill, 2016 provides for the creation of a single regulatory body for health technologies, including medical devices. The functions of this regulatory body are expected to extend to regulation of contractors for medical devices.

While issues to do with quality and use of medical equipment were enshrined in the MES Contract in Kenya, clear regulatory controls would have provided additional clarity and comfort with regard to the quality and standards of equipment to be provided in the interest of patient care.

3.6.2 Stakeholder Engagement

As the MES Project was the first of its kind in Kenya, there was initial resistance particularly from the County Governments and there was need not only for sensitization of all stakeholders but also consideration of the views of various categories of stakeholders in the development and implementation of the project. Given the complex and high profile nature of the MES project, stakeholder engagement was therefore critical to the success of the project. In addition, public participation is a constitutional requirement in Kenya. Accordingly, the Ministry of Health

¹⁶ Public Procurement Oversight Authority, 'Public Procurement Manual for the Health Sector, Kenya' December 2008 available at http://www.ppoa.go.ke/images/downloads/procurement_manual_health_final.pdf <last accessed on 10 March 2017>

conducted stakeholder consultations at both the National Government level as well as at the County Government level so as to ensure that the project obtained both political and social buy-in by Kenyans at large. Not only was stakeholder engagement critical during the project development stage, the MES Contracts have incorporated a strategy for ensuring that stakeholders are engaged throughout the life of the project, by establishing multi stakeholder committees to provide a forum for the joint review of issues affecting the MES Project.

3.6.3 Capacity Building for Local Health Workers

It is widely recognized that in developing countries, lack of skilled, adequate health workforce impedes the achievement of the right to health¹⁷ Ensuring sustainable healthcare by through the MES arrangement can only succeed if there is an adequate, well trained health workforce. The MES arrangement for the supply and maintenance of medical equipment for instance, would require a competent health workforce to operate the equipment. Healthcare personnel are therefore at the core of achieving the SDG on health. One way of addressing this challenge is to include the training of local health workers as one of the obligations of the private party in the MES arrangement. While it is possible to include the provision of clinical services and supply of health workers as part of a MES arrangement, the more sustainable approach would be to build the capacity of the locals, for purposes of long term benefits.

In this regard, the inclusion of training of various cadres of health workers as one of the services to be provided under the Kenya MES arrangement was aimed at maximizing the benefits of MES by ensuring that there was a pool of competent health workers with adequate skills to operate the equipment. The capacity building of locals to operate the equipment supplied under the MES arrangement is a catalyst for sustainable development as it ensures that Kenya benefits not only from having state of the art medical equipment in its public hospitals but that the capacity of various cadres of healthcare personnel is built in various areas.

3.6.4 Contract Management

The MES arrangement would ideally define key issues such as the payment mechanism, agreed service requirements, workflow and timelines for delivery of the various project components. Proper contract management is therefore key in ensuring that the MES arrangement leads to sustained efficiency, thereby providing the expected health gains. The management of responsibility and risk ensures that both the public and private sector entities meet their respective obligations. Further, an effective contract management framework ensures a good working relationship between the parties.

3.6.5 Performance Monitoring

Performance monitoring is fundamental to the MES arrangement as it guides the calculation of payments (and payment deductions) to be made under the contract. As opposed to the utility and

¹⁷ Lassi et al, 'Systematic review on human resources for health interventions to improve maternal health outcomes: evidence from low- and middle-income countries' Human Resources for Health (2016) 14: 10 p.1

transport sectors where the quality of service or performance may be easier to measure, the position is different in social infrastructure such as health services, where outcomes may be harder to measure particularly due to the fact that public interest objectives may not be aligned to the profit making objective of private entities.

While privately financed infrastructure projects exist across various sectors, emphasis has in the past been largely placed on sectors such as utilities and transport, with various studies, toolkits, knowledge data bases e.t.c being developed as a guide for developing and implementing such projects. The same has not been the case in social sectors such as health, where reference materials to guide policy makers are insufficient.

Developing countries such as Kenya, which have little experience in undertaking privately financed social infrastructure projects therefore face challenges in developing a performance mechanism that ensures improved service delivery, while at the same time ensuring that the private sector is incentivized and motivated to provide solutions to the infrastructure challenges facing the various social sectors. There is therefore need for resources, case studies and benchmarks upon which developing countries can rely on, to structure a privately financed healthcare project that guarantees sustainable, efficient service delivery.

3.6.6 Transaction Advisory Services

Prior to embarking on the MES Project, the Ministry of Health had limited experience with privately financed public health projects. In the absence of sufficient capacity within a procuring entity, it is important to engage skilled transaction advisors to provide assistance in the development and contracting for the MES arrangement. The private sector MES providers will usually pay for top-notch advisory services during such a transaction and it is important to ensure that the public procuring entity is equally well represented in developing and negotiating a deal that benefits both parties and that enables the public sector entity to meet its objectives of provision of sustainable healthcare.

As this was the first time the MES model was being implemented in Kenya, and considering the magnitude of the project, it was important to have skilled transaction advisors representing the Government of Kenya and the Ministry of Health so as to ensure success of the project. The transaction advisors provided guidance on compliance with the prevailing legal regime, guided the government in ensuring that it obtained value for money and that there was appropriate risk allocation. While the technical advisors on the Kenya MES project were in house, highly educated and competent Ministry officials, the legal advisory services were outsourced to a leading corporate commercial legal firm, while a leading accounting and consulting firm was appointed to provide financial advisory services. The legal team that advised on the MES Project went ahead to win the ‘Transport and Infrastructure Team of the Year Award’ for successfully advising the Government of Kenya on all aspects of the complex MES Project at the Africa Legal Awards Ceremony held in Johannesburg in September 2016.¹⁸

¹⁸ The African Legal Awards is hosted by *Legal Week* (organisers of The British Legal Awards) and the *Corporate Counsel Association of South Africa* and seeks to recognize exceptional achievement from within Africa’s legal community. The award winning team of Legal Transaction Advisors on the Kenya MES Project was Iseme Kamau and Maema (IKM) Advocates, a leading Kenyan law firm, in collaboration with its affiliate firm DLA Piper, which is a London based firm with extensive experience in advising on MES projects in various jurisdictions.

3.7 Benefits of the Kenya MES Project

While the project is currently in its second year of a seven-year contract, the benefits on the health sector are already being felt. The ninety eight (98) hospitals under the MES project have benefitted from specialized, modern, state of the art medical equipment, and citizens can now enjoy access to quality specialized healthcare across the country. Services which were previously largely only available at the national referral health facilities such as dialysis treatment is now available in health facilities across the country and patients do not have to travel long distances to the major health facilities for treatment.

As the MES Contract contains strict performance parameters, with up to 98% up time guarantee on the equipment, this has increased efficiency in hospitals and healthcare workers can now focus on actual service delivery, as repairs, maintenance and replacement of spare parts of the medical equipment is the responsibility of the MES providers.

As part of the MES arrangement, one of the contractors has since established a Healthcare Skills and Training Institute in Kenya, which is a dedicated healthcare skills advancement center aimed at building capacity of various cadres of health workers in Kenya, for the term of the MES contract.

4.0 Conclusion and Possible Areas of Interest for UNCITRAL

Progress in achieving the SDGs would be enhanced by improving the capacity of states to develop, implement and monitor project financed infrastructure projects aimed at delivering key social infrastructure, such as healthcare. While UNCITRAL's Legislative Guide on Privately Financed Infrastructure Projects as well as the Model Legislative Provisions on Privately Financed Infrastructure Projects provide useful guidance for the development, implementation and monitoring of privately financed infrastructure projects, developing countries could benefit from a toolkit or a guide containing best practice principles not only for healthcare projects, but also the importance of promoting partnerships with the private sector and other key players in achieving the SDGs.

Emphasis has in the past been placed on developing resources, toolkits, knowledge data bases etc on privately financed infrastructure projects in the utilities and transport sectors. The same has not been the case for social sectors such as health, where policy makers do not have access to a wide range of resources, case studies and benchmarks upon which they can rely on. UNCITRAL could therefore consider including guidance on involving the private sector in the development, implementation and management of social infrastructure.

As opposed to the utility sectors where the quality of service may be easier to measure, in social infrastructure such as health services, outcomes may be harder to measure particularly due to the fact that public interest objectives may not be aligned to the profit making objective of private entities. Structuring of social infrastructure projects such as those in the health sector would therefore require the right balance between achieving the public interest objective and ensuring that private sector is incentivized and motivated to provide solutions to the infrastructure challenges facing the various social sectors. UNCITRAL may consider developing guidance on rules and regulations relating to service and support with regard to health equipment, so as to

ensure that as developing countries implementing projects in the health sector are in a position to monitor performance of the private sector, based on a set of generally accepted standards.