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Use of Medical Devices Quality Standards to Improve Health Care Technology Management in KSA

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Abstract - My research focuses on quality standards of medical devices and human resources; this allows to perform an assessment of health care technology management (HCTM) and to draw conclusions to improve HCTM. Thus, the implementation of quality standards in HTM emphasizes the potential contribution of this application to decision-making and evidence-based policy making. This article aims to: a) Present the main objectives of health technology management (HTM). (b) Present strategic actions to promote the development of health care technologies in Saudi Arabia. (c) Promote informed decision-making on the introduction of HT assessment into Health system (HS) in Saudi Arabia. We conclude that HTM enable hospitals to provide better care for their patients, starting with adequate procurement to include all lifecycle aspects including training equipment users, maintaining devices and managing compliance. At the same time reducing, the costs related to HTM of at least 30% compared to their current yearly expenditures. This can be achieved through the reduction of portable assets stockholding, improved investment planning and reduced procurement costs. Reduce expenditure on consumables; improve utilization of Healthcare Technology, reduce stockholding of associate spare parts and better user training.

Key Words: HCTM, Medical devices quality standards, HTMA, decision-making

1. INTRODUCTION

In both developed and developing countries, health systems (HS) face a challenge: delivering health care in a context of high resource constraints. New health policies, practices and decisions are needed to increase the positive impact of health interventions on the health of populations, while maximizing the cost-effectiveness of expenditure incurred by these interventions. This article shows how the application of quality standards can be adopted and adapted to promote health equity. This study focuses on health care technology in Saudi Arabia. And the impact of applying quality standards to improve the management of health technology (HT).

In the health field, the term HT refers to pharmaceutical products, supplies, equipment and medical devices; medical and surgical procedures; public health programs and support systems; the management and organization systems used in prevention, screening, diagnosis, treatment and rehabilitation.

My research focuses on medical devices and human resources, based on relative quality standards; this allows me to perform an assessment of HTM and to draw conclusions to improve the HTM.

1.1 Standards and *Goals*

Based on Hospitals ESR CBAHI Standards quoted below:

1. The hospital has a process for proper credentialing of staff members licensed to provide patient care.
2. Medical staff members have current delineated clinical privileges.
3. Policies and procedures guide the handling, use, and administration of blood and blood products.
4. Patients at risk for developing venous thromboembolism are identified and managed.
5. The hospital has a process to ensure correct identification of patients.
6. The quality standards require a medical device files (1).

Organizations should develop and maintain a medical device file for each product type or device family. Sub-clause 4.2.3 of ISO 13485:2016 sets requirements for various elements that should be incorporate in the medical device file. These include:

a) Establishment and maintenance of a file for each device family –
b) Keep reference documents showing conformity –The reference can be a Quality Manual that is based on ISO 13485 and relevant regulatory requirements.
c) Incorporate a description of each family –
d) Develop and maintain procedures for each medical device family –
e) Develop and maintain specifications and procedures for measurement of products –
f) Document procedures for servicing and installation

Thus, the implementation of medical device and human resources quality standards in the management of HT underscores the potential contribution of this application to evidence-based decision-making and policy development (2). This article aims to:

a) Present the main objectives of HTM.
b) Present strategic actions to promote the development of HT in Saudi Arabia.
c) Promote informed decision-making on the introduction of HTA into HS in Saudi Arabia.

Approach

HTM includes areas such as procurement (replacement planning), consumables management, service delivery, decontamination, equipment library, user training, telehealth platforms, providing a complete technology platform for an active national HS (2).

a) The main objectives of HTM are the following:

- Financing and management of equipment replacement
- Management of current and future costs
  - reducing of overall costs
  - Reliable equipment replacement forecasts
  - Optimization of cash flows
- Improve the patient care experience
  - Increase patient safety through standardization
  - Reduce unnecessary hospitalization in home care (telehealth).

The ultimate goal of HTM is to enable hospitals to provide better care for their patients while reducing HTM costs over their current annual expenditures. This can be achieved by reducing the stock of assets, improved planning of investments and supply costs, reduced consumables costs, improved use of health technology, reduced storage of spare parts associated, better user training. The following figure 1 summarizes the basics of HTM, starting with procurement, to include all aspects of the lifecycle, including equipment user training, device maintenance, and compliance management.

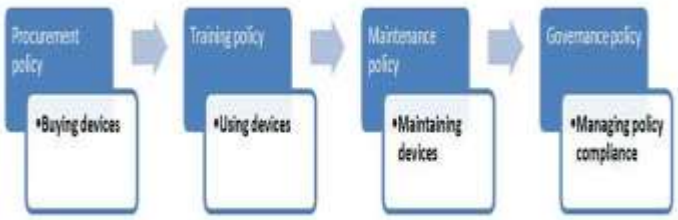

Figure 1. Medical devices lifecycle on HTM

Ultimately, adopting a professional approach to HTM complies with regulatory standards for medical device management, guides best practices for medical devices management policy, and leads to improved practice through improved management.

b) Strategic actions to promote the development of HT in Saudi Arabia.

1) Implement the HTM to save money and lives

Hospitals was always been confronted with fundamental issues of patient safety, care and budget issues. The serious problem of medical device management has been recognized more and more recently, covering the areas of procurement, training, maintenance and governance. Procurement for these organizations can be redefined, facilitating training, maintenance and governance, reducing risk and costs (figure 2).

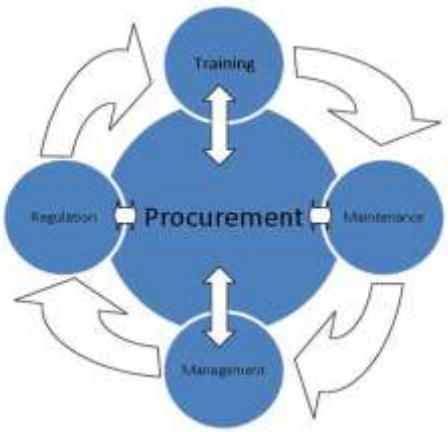

Figure 2. Medical devices management

A poor procurement leads to variations and ultimately to a higher risk for the patient. This is recognized by the research done by the World Health Organization.

Improved procurement practices will inevitably reduce costs and will help improve equipment use and maintenance practices. In summary, good procurement reduces the variety of equipment types, enabling more efficient user training, more efficient maintenance and achievable economies of scale, thereby reducing costs. Another added benefit is that risks associated with the use of equipment can be reduced, making it a safer environment for patients.

The overall outcome of this strategy is the improvement of HCTM within a governance framework that meets the needs of patients, regulators and the management of the organization.

2) Train users to improve patient care

International data shows that user errors are one of the leading causes of incidents involving medical equipment. User training is therefore a fundamental element for the correct and safe use of medical equipment. In addition, skilled users make better use of their equipment, increasing productivity and reducing breakdowns and maintenance requirements. That's why user training is a key part of HTM.

HTM is a concept based on academic research and conducted in collaboration with other reputable organizations, including the SFDA; CBAHI; MHRA and the World Health Organization.

3) Plan the replacement of medical devices for more efficient HCT

Hospitals do not have the funds to replace aging assets that would provide improved service. Even with support of states, the National HS fleet is aging rapidly. A flexible but planned approach to equipment replacement is needed and could lead to standardization benefits such as: (figure 3)

- Easier user training / better use of technology
  - Safer and improved services for patients
    - Faster diagnosis and therapy
    - Less complications
    - Early discharge
- Easier/cheaper Maintenance
  - Newer equipment is more reliable / less breakdowns / more uptime
  - Less spare parts usage
  - Economies of scale
- More economic
  - Improved utilization with improved training and maintenance
  - Less equipment needed
  - Improved use of technology software leading to admittance avoidance and early discharge (potentially freeing up emergency beds leading to more income generating elective work / easing bed pressures / avoiding cancellations)

Figure 3. Strategic actions planed for medical devices replacement

To promote the development of HT in Saudi Arabia by applying the strategic actions cited before, we adapt the strategy of HT assessment in HS of this country to specific context for an informed decision-making.

Method: from HTM Assessment (HTMA) to informed decision-making

The concept of HT assessment emerged in response to the concerns of policy makers who were wondering how to avoid the uncontrolled spread of costly medical devices. Its main objective is to inform decision-making in the field of HT. In this way, national governments can seize opportunities and overcome HT challenges by optimizing their decision-making processes, recognizing the central role of innovation, taking into account hazards, and finally implementing and coordinating HTA and broadcasting the results (OECD (3)).

It should be noted that assessment includes often, but not always, an economic analysis. This can for example take the form of cost-benefit analysis, cost-utility analysis, cost-effectiveness analysis, cost minimization analysis, budget impact analysis etc.

The regulation, assessment and HTM are complementary functions that ensure the proper introduction and use of medical devices.

Best practices in HTA are based on a number of elements of this model (4)
• HTA adapts global knowledge to different components of the HS, such as human and material resources, as well as relevant data obtained from different health contexts.
• HTA promotes transparent decision-making and, as a result, the participation of all stakeholders including civil society.
• A needs-based and equity-based assessment of HT enables decisions to be made in the general spirit of fairness and accountability.

The HTA is intended to support the deployment of cost-effective new technologies, to prevent the adoption of unhealthy technologies for HS and to curb the adoption of technologies that look promising whose reliability remains uncertain.

From this perspective, HTA is sometimes used to require additional evidence of the advantageous cost-effectiveness of a technology before deciding on the support of that technology (5).
One of the key tasks in improving the quality of health systems worldwide is to put in place mechanisms to convert knowledge into action. Such mechanisms require the involvement of all the different partners, all of whom must strive to develop evidence-based policies and applications (6).

Lavis et al. (7) analyzed this institutional framework for evidence-based health policy in developing countries. The authors indicate seven recommendations given to responsible leading organizations that promote the use of research-based data to develop a health policy (figure 4):

1) Collaborate with other organizations;
2) Establish close links with policymakers and involve relevant stakeholders in the work;
3) remain neutral and manage conflicts of interest between the parties involved in the work;
4) Build the capacity of those who work within the organization;
5) use good methods and ensure the transparency of work;
6) Start small, target specific people and goals, and address important issues;
7) And be attentive to the implementation, even if it is not within their competence.

In HTA, it is therefore necessary to "globalize the information and locate the decision" (8).

The development strategies adopted for HTA are:
1. Adaptation of strategy to the specific context,
2. Define priorities for HTA,
3. Strategy based on focal points for the HTA,
4. Rely on synergistic meshes.

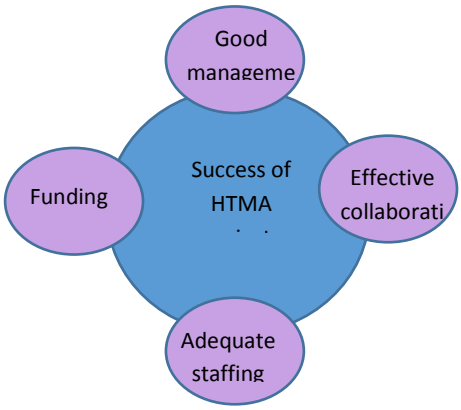

Figure 4. Factors for Success in Implementing HTA Projects

Finally, the HTA process is intended to assist health policy decision-making. During this phase of the process, policy makers review information collected and evaluated by the HTA agency. Although decisions are supposed to be made independently of the HTA organization, the way in which they are made will affect the HTA process (9). For example, if there is an opportunity to challenge decisions, the HTA may need to conduct more in-depth analysis. If decisions are made using an expert panel, the HTA organization may need to coordinate the committee or attend its meetings.

Results

In view of CBAHI's specified quality standards for medical devices and human resources, which are the subject of our study, and based on the objectives cited above and the HTM assessment approach, we found that the use, maintenance and governance of medical equipment was based on a central issue, namely, procurement practices. HTM's procurement practices facilitate training, maintenance and governance, reducing risk and costs. This requires structured procurement teams with the appropriate skills and tools and close relationships with OEMs and suppliers (establishing list of approved suppliers).
In Saudi Arabia, the replacement value of all medical equipment in the national health system is estimated at SR 13 billion.

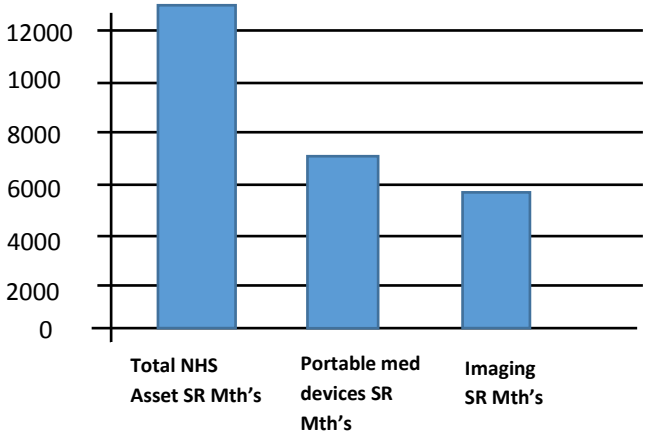

Figure 5. Budget allocation for medical devices replacement on NHS

Hospitals must manage their HCT, which includes equipment, consumables, user training, maintenance and regulatory compliance.

Evidence shows that there is increasingly problematic not to replace HT because of a lack of funding. In many National HS organizations, more than 40% of devices have already exceeded their recommended life.
This means a need of investing in HTS. The total value of the assets of the National HS is about 13 billion SR, of which 5.72 billion SR of fixed capital and 7.28 billion SR of portable equipment.

The current "improvised" National HS methods of purchasing "on demand" HCT for the purpose of saving money actually lead to less standardization, to a significant age variance, making wholesale purchases difficult, ultimately leading to higher costs, and higher risks to patients. The current annual investment required for HCT in National HS amounts to about 27 Billion SR.

Conclusion

Mismanagement of the technology leads to an estimated investment backlog for equipment replacement greater than SR 4 Billion in 2015, with increased risks for patients and increased costs because old technology was less efficient and reliable than new technologies.

The SFDA recognizes that National HS equipment is very poorly used, with many devices inactive. Improving the use of technology can reduce the amount of assets required and thus reduce costs by up to 30%, resulting in a significant reduction in the investment required to replace devices and software. If the National HS improves the TM, it can effectively reduce costs by standardizing and maximizing usage.

Our research shown that adopting the professional HTM has resulted in savings of more than 30%. Various government agencies such as the SFDA and CBAHI recognize that the National HS does not manage the technology in accordance with best practices and has provided advice on improvements.

This allows decision-makers in the future to favor the deployment of cost-effective new technologies and to provide the population with better patient care solutions while reducing the costs associated with the management of HCT in Saudi Arabia.

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