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EVALUATION OF MEDICAL DEVICES AND CONSUMABLES: THE PROCESS AND THE CHALLENGES FROM THE JORDAN ROYAL MEDICAL SERVICES PERSPECTIVE. IS THERE A NEED FOR HTA INTERVENTION?

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ABSTRACT

Background: In healthcare practice, to maximize the benefits of the available resources, it is economically unjustifiable for a decision-maker to adopt a new medical technology without an evaluation and comparison to the existing alternatives. Several healthcare organizations are revising the process of evaluating the medical devices (MDs) and medical consumables (MCs) in order to deal with the existing flaws, particularly after the global efforts to integrate the health technology assessment (HTA) in the protocols of evaluation. **Aim**: To describe the current process of assessment of MDs and MCs in Jordan Royal Medical Services (JRMS) and to address the challenges that face the procedure; in addition, to attract the appropriate attention of the importance of HTA in the process of evaluation; finally, to clarify the opportunity for improvements in the current procedure to make the decision of adoption more transparent and robust. **Methods**: The study was conducted in the Directorate of pharmacy and medical supply /division of medical consumables supply in collaboration with HTA unit in the JRMS, Amman, Jordan. In this study, the researchers fully described and revised each step of the current practice of MDs and MCs evaluation applied and approved in the JRMS in 2024. In addition, the study demonstrated the rationale behind the application of HTA in the evaluation process. **Results:** In JRMS, after submitting an evaluation file by the local agent, the evaluation of MDs and MCs is performed through an expert's panel. The evaluation assesses the effectiveness of the product compared to the current practice. Typically, no cost considerations are included in the assessment of the MDs and MCs. **Conclusions:** In JRMS, the evaluation of MDs and MCs is completely depending on the comparative effectiveness of the product. Generally, no cost-effectiveness assessment is conducted for the new of MDs and MCs. The researchers recommend further considerations for setting a protocol for involving the HTA unit in the assessment of the new innovative technologies of MDs and MCs, specially the products with high impact on the budget, before adopting them.

KEYWORDS: Medical devices, medical consumables, evaluation, HTA.

INTRODUCTION

In healthcare practice, to maximize the benefits of the available resources, it is economically unfeasible and unjustifiable for a decision-maker to adopt a new medical technology without an evaluation and comparison to the existing alternatives.[1] The majority of healthcare institutions carry out different approaches of evaluation for new health technologies before adopting them.[2] The assessment of pharmaceutical technologies is standardized and consistent throughout different healthcare institutions due to the availability of standard assessment guidelines.[3] However, the evaluation of medical devices (MDs) and medical consumables (MCs) is a distinctive and relatively complicated process.[4] Complexity is attributed to MDs and MCs unique features, such as rapid and incremental innovation, lesser barriers to market access in addition to inadequately regulated pricing methods.[3, 5, 6] Accordingly, the evaluation of MDs and MCs in many institutions assesses the effectiveness rather than the cost-effectiveness of the new technology.

Unlike the evaluation of pharmaceutical products, several outcomes measured in the evaluation of medical devices (MDs) and medical consumables (MCs) may not be expressed directly in terms of quality of life of patients.[7] The outcomes could be related to the institution or the user of the new technology. For example, new easier surgical procedure for surgeons could give the same clinical outcomes in shorter surgery

time. Then the ultimate outcome might be increased availability of surgery theatres.

Several healthcare organizations are regularly revising the process of evaluating the MDs and MCs in order to deal with the existing flaws and to incorporate the essential improvements particularly after global efforts to integrate the health technology assessment (HTA) in the protocols of MDs and MCs evaluation.[9]

The Jordan Royal Medical Services (JRMS) is a publically funded healthcare provider in Jordan. Within JRMS, the Directorate of pharmacy and medical supply performs a unique process of assessment for new MDs and MCs. This process depends primarily on a list of required documents submitted by the company. Then the evaluation will be completed by assessing the effectiveness through an expert panel of end users.

METHODS

This study was conducted in the directorate of pharmacy and medical supply /division of medical consumables supply in collaboration with HTA unit in the JRMS, Amman, Jordan. The study fully described and systematically revised each step of the current practice of assessment of MDs and MCs applied and approved in the JRMS in 2024, in order to address the challenges that face the procedure. In addition, the study made an effort to demonstrate the importance of HTA in the process of evaluation. Ultimately, the study revealed the opportunity for improvements in the current procedure to make the decision of MDs and MCs adoption more transparent and robust in JRMS compared to the available literature and published practice. This study was approved by the institutional review board (IRB) in JRMS in its meeting number (7/2024).

RESULTS

The process of evaluation of MDs and MCs in JRMS starts with submitting an evaluation file, by the local agent of the manufacturer, to the directorate of pharmacy and medical supply /division of medical consumables supply. Documents stated in table (1) should be attached to the submitted file. These required documents were set by the high medical consumables evaluation committee (HMCEC). This list was set according to an accumulative experience of evaluation process in the institution over time. It was subject to many amendments to keep it up to date. The documents attached to the file are then reviewed by a pharmacist officer within the department and approved by a senior pharmacist officer, usually a member of the HMCEC, to assure that they meet the standards required in the list.

Table 1: Documents required for the evaluation process of MDs and MCs in JRMS.

Document	Document approval requirements
Covering letter from the local agent	None
Certificate of origin	Original document or a certified copy from the chamber of commerce in the country of origin
FDA certificate for products of USA origin CE or FDA certificate for products of non-USA origin GMP certificate for products of Jordanian origin	Original document or a certified copy from the Jordan food and drug administration (JFDA)
Free sale certificate in the country of origin, in addition to a free sale certificate from one of the countries approved as reference countries.	Original document or a certified copy from the chamber of commerce in the issuing country.
Published studies regarding the effectiveness of the product. Commercial product catalogues	None
Authorization letter from the manufacturer to confirm that the local agent is representing the manufacturer in Jordan.	None
Product registration, importation permission or product trading permit from the JFDA	None

Some MDs and MCs have special requirements. These products are cardiac and peripheral stents, cardiac pacemakers, cardiac valves and rings in addition to vascular grafts and patches. In order to be evaluated in JRMS, these products should be FDA approved regardless the country of origin.

Consent from head of the relevant speciality should be granted before proceeding in the process of evaluation. The head of relevant speciality should provide his medical opinion regarding the new technology, agree to perform the evaluation process in the department and suggest the quantity of samples that would be sufficient to provide a precise and fair judgement for the evaluation process.

It is essential to mention that the evaluation of MDs and MCs used to be a free of charge process. However, since the beginning of 2023, the JRMS started to charge a fee for the evaluation procedure. A fee of (JD 250), approximately (USD 352), per each item should be paid by the local agent to the financial department after the initial acceptance of the documents.

Following full assessment of the evaluation file, obtaining the consent from head of speciality and collecting the fees, the file is submitted to the HMCEC.

The members of the committee are designated by the directorate general of the JRMS and represent deferent medical specialities in the JRMS, in addition to representatives from the directorate of pharmacy and medical supply.

The HMCEC holds its meetings periodically, usually on monthly basis. Each file submitted to the committee is discussed by the members to provide a decision on the importance and necessity of the submitted items in order to proceed in the process. In specific cases, the HMCEC may request for the approval of the institutional review board (IRB). These cases include, for example but not limited to, implantable MDs and MCs. If the committee finds any added value to the system from the evaluation process, it decides to invite the local agent to provide the samples for assessment.

The samples are attached to a formal letter from the directorate of pharmacy and medical supply and sent to the division of pharmacy and medical supply in the hospital. Samples are then dispensed to the appropriate department whiten the hospital according to the previous approval from the head of relevant speciality.

Time needed for complete assessment depends on the type of MDs and MCs. Some items may involve a relatively longer time to provide full and fair evaluation due to long-term outcomes of the product.

The assessment of the MDs and MCs in the department should be conducted and revised by at least three specialists. The decision, then, has to be confirmed by the head of the speciality and approved form the relevant director, for instance, director of the hospital or the director of the speciality department.

The finale assessment conclusion should be reported in an "evaluation form". This form contains a number of cells that should be filled, for example, trade name of the MDs and MCs, size, pack, manufacturer, number of samples used in the assessment, the technical rationale behind the decision and the signatures and stamps of the assessing specialists. The ultimate assessment decision should be summarized in the "evaluation form" by selecting one of the following alternatives: a- Equivalent b- Inferior c- New technology (should specify if it is recommended or not recommended new technology). The final assessment result has to be selected in comparison to the current practice in the speciality.

The evaluation form is then attached to a formal letter from the hospital and sent back to the directorate of pharmacy and medical supply. Afterwards, the assessment decision is approved by the general director of JRMS, then, the local agent is informed of the final evaluation result.

DISCUSSION

In JRMS, the acceptance of the evaluation file of MDs and MCs is completely depending on presenting a list of required documents. If the local agent failed to submit any of the documents, the product would not be able to go through the evaluation process, with no exceptions for that standard from the HMCEC. The required documents list was set by the HMCEC according to an accumulative experience of evaluation process in the JRMS over time. The list was amended few times to deal with the developments occur in different fields, for example local or global trade agreements which may affect the certification of the documents. However, this list is considered by some parties as a barrier for adoption of new technologies, specially, in case the local agent failed to submit any of the required documents for evaluation. According to this opinion, this may reduce the competition between manufacturers in the procurement process.

Consequently, one of the frequent arguments, that if a new technology is registered through the national authority, JFDA in this case, the new technology should be made available to all patients, i.e. the decision of adoption should be the "unmet needs" of the institution with no barriers to entry. On the other hand, different arguments set huge reservations against the adoption of any new technology due to financial restrictions. Accordingly, between the two extreme arguments, as many other publically funded healthcare organization, JRMS needs a more transparent technique that facilitates the decision of resources allocation and adoption of new technologies.

Since healthcare organizations are not able to make all new innovative technologies available, mainly due to limited financial resources, they are forced to set up different barriers to entry (8). The list of required documents and fees charged for the evaluation procedure are examples in JRMS.

Although the assessment of MDs and MCs in JRMS is conducted and revised by at least three specialists, it still has no standard criterion except the "comparative effectiveness". The evaluation assesses the effectiveness of the product compared to the current practice; and consequently, the end result of assessment is summarized into one of the following choices: equivalent, inferior or new technology (should mention if it is recommended or not recommended new technology). Typically, no cost considerations are included in the assessment of the new health technologies; therefore, no cost-effectiveness assessment is conducted for any innovative MDs and MCs.

Economic evaluation and health technology assessment (HTA), including cost-effectiveness analysis, are techniques that were created by health economists to conduct a transparent and robust judgment process for new health technologies. The ultimate goal of HTA is to

advise the decision maker about resources allocation. HTA, typically, measures costs and outcomes of health alternatives and give an "evidence-based" recommendation regarding the new technology.

In 2019, HTA unit were established in the JRMS. The unit was involved in many pharmaceutical products cost-effectiveness analysis. Despite the fact that some MDs and MCs are considered an "expensive" technologies and have high impact on the organization budget, the unit conducted fewer number of analysis for MDs and MCs. This may be due to many reasons; mainly the complexity of analysis for MDs and MCs and secondly for the reason that the unit was not invited to be a part of the analysis, On the other hand, the high committee of the medications requested the HTA unit to conduct many economic evaluations for different pharmaceutical products. The recommendations form the HTA unit may affect the prioritization decision of resources allocation.

CONCLUSIONS

In JRMS, the evaluation of MDs and MCs is completely depending on the comparative effectiveness of the product. Different regulatory barriers were set by healthcare organizations to regulate the process of MDs and MCs adoption, a list of required documents and fees charged for the evaluation procedure are examples in the JRMS. Generally, cost considerations are not included in the assessment process in JRMS, therefore, no cost-effectiveness assessment is conducted for new MDs and MCs. The researchers recommend setting a protocol for involving the HTA unit in the assessment of the new innovative technologies of MDs and MCs, specially the products with high impact on the budget, before adopting them.

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