Strategic Budget Planning for Complex Medical Devices: A Case Study on Surgical Microscopes

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***Abstract*— Dramatic developments in medical device technologies, significantly influences the cost of equipment acquisition and operating expenses. Sometimes the budget estimation needed for rudimentary medical equipment can be complicated, even more so for a complex device with several add-on features. In Canada, the budget allocated to capital equipment purchases is challenging because the budget comes from the provincial government to the hospitals. The capital equipment budget amount is challenging because of the public healthcare funding model, whereby fiscal budgets come from the provincial government to the hospitals. The capital equipment budget allocation is limited and restricted in hospital as "big ticket" items compete with other capital requests. Having a strategic budgeting plan, completed by a clinical engineer ensures a sufficient budget for the capital request.**

A strategic budgeting plan was central to this study to estimate the required funding for replacing aged existing surgical microscopes at the Children's Hospital of Eastern Ontario (CHEO). This study demonstrated the development of a methodology to guide budget planning and includes inventory assessment, market analysis, the identification of clinical requirements, cost analysis, and the utilization of the outputs of these steps for capital planning requests. A basic step-by-step approach can be followed by any clinical engineering department before submitting a capital planning request for complex medical devices.

Index Terms*— Capital request, medical equipment, replacement plan, strategic budget planning, surgical microscope.

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I. Introduction

Hospitals and healthcare systems have a continual need to replace medical equipment which pass their life cycle, as the medical device is no longer cost-effective, safe, and clinically relevant or may no longer meet the standard of care. Although Canadian hospitals have been allocating a significant portion of their resources to the acquisition and management of capital assets, most hospitals do not have sufficient capital budgets to approve all requests for equipment replacement [1]. Hence, to better use a hospital's budget, it is imperative to have a strategic plan to prioritize all medical equipment for replacement. The children's Hospital of Eastern Ontario (CHEO) has its own strategic plan for the replacement of existing equipment. Based on an established set of quantitative and qualitative criteria such as safety, supportability, equipment condition, and clinical impact equipment is evaluated, and replacement timelines are defined, and the equipment is prioritized in a replacement plan [2]. After completing the replacement plan, the next step is to proceed with capital budget requests.

At CHEO, there are 5 existing surgical microscopes across three different modalities, Neuro Spine, Ophthalmology, and ENT (Ear Nose and Throat), and two clinical microscopes in ENT clinic were identified to be replaced in the next three years by the Clinical Engineering team. The aforementioned criteria were used in developing a replacement plan for the existing surgical microscope. To evaluate the equipment condition criterion, we should consider age and work orders related to the equipment. The standard life cycle of surgical microscopes is 10 or 12 years, for portable or fixed ones respectively since the former are more susceptible to wear [3]. The average age of the existing surgical microscopes at CHEO is 17 years, indicating that all surgical microscopes have outlived their life cycles. Moreover, CMMS work orders related to the existing surgical microscopes indicated that even though preventative maintenance has been performed on this microscope, the number of corrective repairs and corrections is relatively high cost. Thus, it is more cost-effective to replace the equipment than to maintain it. In regard to supportability criterion, CHEO has received "End of Support" and "End of Life" notices for existing surgical microscopes which mentioned that due to the obsolescence of numerous parts [4], the support services for this equipment are no longer available. As for clinical impact, a surgical microscope can be utilized in more than 100 cases annually, and varieties of surgeries rely on this equipment, therefore if the device fails, it may lead to excessive downtime, or repair may not be possible.

II. Background

Part of strategic budgeting plan should be understanding the basic function and features of medical equipment, the next section provides a technical review of surgical microscopes. A surgical microscope is an optical tool that offers a high-quality magnified and illuminated view of the minute structures in the surgical area for a surgeon, surgical microscopes play an important role in the fields of otolaryngology (also known as ENT), neuro spine, ophthalmology, plastic and reconstructive surgeries. Currently available surgical microscopes are precision instruments with a number of attractive properties and capabilities.

This paper will introduce the basic system of a surgical microscope and explain features and technologies that have been adopted to contemporary surgical microscopes [5].

A surgical microscope can be divided into three main parts which are required for the performance of the microscope: An optical system, an illumination system, and a supporting structure.

A. Optical System

The optical system is the primary factor for the image quality produced by a surgical microscope. Fig. 1 shows the optical components of a basic microscope include binocular head, eye pieces, a magnification changer or zoom changer and the objective lens. All four of the microscope's optical parts contribute to the overall magnification of a surgical microscope. Current surgical microscopes have a manual or motorized magnification changer that allows the user to choose magnification ranges between 4x and 40x. A microscope head usually has one main observation port and one rear or lateral port for co-observers, who can be assistants, students, or trainees [6]. Cameras or other imaging systems can also be adapted to these optical ports for video recording or photography of the ongoing surgery. All optical ports offer an identical field of view (FOV), which are better than surgical loupes and enables “cosurgery”. A 2D/3D camera and monitor are used for sharing the high-resolution view and enlarged stereoscopic images.

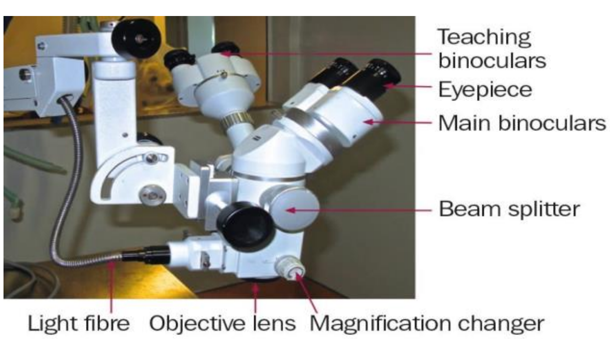

Fig. 1. The optical system of a surgical microscope [4].

B. Illumination System

In addition to the optical system, illumination is vital to the image quality of a microscope. During surgery, a clear and bright view of the entire surgical site is always desired**.** Modern microscopes use high-powered light sources with steady light intensity and the light source is placed distant from the microscope to prevent heating of both the microscope optics and surgical site. The illumination from the light source is transferred through a fiber guide to the microscope, then goes through the objective lens to illuminate the surgical field. Standard light sources for surgical microscopes are halogen light bulbs, xenon light bulbs and light-emitting diodes (LED). LED is designed to provide illumination in the visible wavelength range with high brightness, excellent stability, high durability, less power consumption, and exceptionally low heat. Therefore, it is the gold standard for many ophthalmic and ENT microscopes. However, LED has drawbacks as a surgical light source: higher color temperature and a smaller wavelength spectrum make the light less similar to sunlight. Its spectrum is inadequate for fluorescence-guided applications, in particular fluorescence imaging. Xenon and halogen lamps are two alternatives for satisfying these requirements. Xenon light has a color temperature close to that of sunlight. Thus, the bright-white light can provide a view of the anatomy in its natural colors [7].

C. Supporting Structure

Mechanical stability is one of the most important selection criteria for a surgical microscope. Surgical microscopes should be easy to position and remain steady once the position is selected. Several suspension structures and balancing devices have been designed to quickly and precisely balance the microscope. There are four different supporting structures: (i) on casters (floor stand), (ii) wall mounted, (iii) tabletop, and (iv)ceiling mounted. Fig. 2 shows two different supporting structures are being used in the operating room. The caster stand is the most widely used support structure due to better mobility. However, a wall mount or ceiling mount can assist with space management. A top table microscope commonly used for training purposes. Moreover, many types of controls are available on surgical microscopes to facilitate their use and free surgeons' hands during procedures. Footswitch devices for producing control commands, touchscreens for operating mode selection or intraoperative image switching, and joystick controls for very precise micro positioning are frequently seen on contemporary surgical microscopes. Mouth switch, eye control voice control are alternative methods to control a surgical microscope [8].

(a) (b)

Fig 2. (a) A ceiling mounted microscope [9], (b) A floor stand microscope [10].

Besides these three main components, modern surgical microscopes are equipped with a variety of intraoperative imaging modules, including fluorescence imaging, optical coherence tomography (OCT) and useful intraoperative tools such as toric navigation and wide-angle viewing systems and digital endoscopes, which allow surgeons to perform complex surgeries and enhance surgical results.

In addition to the integrated systems, for performing certain surgeries, surgical microscopes need be coupled with other equipment such as a CO2 laser that needs to be attached to the microscope using an adaptor, endoscopic and surgical navigation systems requiring their modules on the surgical microscopes.

1) Fluorescence imaging

Distinguishing between different tissues especially in neurosurgery can be challenging even with the excellent optics. Fluorescence imaging is an essential tool for enhancing visibility and has been shown to be beneficial for brain tumor resection and intraoperative blood vessel imaging. Because various kinds of tissue absorb varying quantities of fluorophores when exposed to excitation light, with an observation optical filter, the surgical site will show in certain colors and because of the contrast that is supplied by exogenous fluorescent dyes, various types of tissues may be differentiated by the human eye. Fig. 3 shows a fluorescence system includes a camera, an excitation light source, and two filters (one short-pass and one long-pass). The Fluoresce dyes that use are 5-aminolevulinic acid, Sodium fluorescein (Na-Fl) and indocyanine green ICG, a surgical microscope needs to be built with specific filters to be able to visualize each fluorescence dye [11].

A fundamental necessity is the ability for surgeons to switch from white to excitation light, the fluorophores are excited when the illuminating light passes through the excitation filter and causes them to emit light with a certain wavelength.

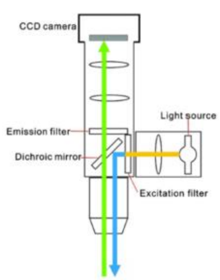

Fig. 3. This illustration depicts a schematic of a surgical microscope integrated with intraoperative fluorescence imaging technology [12].

2) Optical Coherence Tomography

In the field of ophthalmology, OCT has quickly become the standard for both diagnosing diseases and monitoring treatment progress which is a minimally invasive noncontact imaging method. Submillimeter spatial resolution and subsurface information are provided by OCT, making it a valuable tool for structural assessment and surgical instrument positioning. The OCT detects the scattered light from tissue in a process similar to an ultrasound but using light waves rather than sound waves. There are three different intraoperative OCT devices: handheld OCT (HHOCT), needle-based probes, and microscope-integrated OCT (MIOCT).

To use an HHOCT device over the patient's eye, surgeons must first remove the surgical microscope. Needle-based probes can be used when surgeon is operating with surgical microscope. However, a surgical assistant may be needed to hold a needle-based probe, and maybe more instrument ports, during surgery. But microscope integrated OCT (MIOCT), provides OCT imaging of live surgery without interfering with the surgeon's workflow [12].

(a) (b)

Fig. 4. MIOCT systems. (a) Zeiss RESCAN 700 (b) Leica Microsystems Bioptigen EnFocus [13].

The required futures were selected for each modality based on the CHEO needs. We have focused on ophthalmology microscope as an example throughout this article.

Following are selected features for that ophthalmology microscope: a system on floor stand with intraoperative OCT, an integrated 3D camera and 3D monitor, a xenon lamp, a wireless Foot Control Panel, a toric navigation, and a wide-angle viewing system.

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III. Methodology

Medical equipment budget planning is an important process for a healthcare facility. When properly executed, it ensures the availability of adequate approved budget. Additionally, by assisting the choice of cost-effective technologies, it optimizes the use of the hospital’s capital resources and improves the quality of patient care by ensuring that equipment is not only up-to-date and functional but also meets facility needs. Components of medical equipment planning include the following in this order:

1) *Inventory assessment*
2) *Market analysis*
3) *The identification of requirements*
4) *Cost analysis*

In this article, we discuss the general principles behind each component and describe how they help with budget planning for the existing surgical microscopes at CHEO.

1) Inventory assessment

It's important to have a starting point before moving forward with any sort of planning or budgeting. Data sets will be helpful to understand the medical equipment we have and replace it with what our organization needs. Thus, the first step is looking at the inventory of specified equipment. The inventory should consist of all basic equipment data such as the type and number of equipment, manufacturer's name (make), model number, installation type, location, and age of the equipment currently in use. The information can be extracted from hospital CMMS (Computerized Maintenance Management System), which is a medical equipment database that contains information about all medical equipment of an organization. It is also used to collect, store, report and analyze data regarding maintenance and repair of medical equipment. Thus, a complete and accurate CMMS data is the key means in this component [14]. For this assessment, the inventory of current surgical microscopes at CHEO was retrieved from CHEO's CMMS. Table 1 shows a list of existing surgical microscopes at CHEO.

TABLE I
EXISTING SURGICAL MICROSCOPES AT CHEO

Modality	Make	Model	Installation type	Location	Equipment Age
Ophthalmology	Zeiss	OPMI VISU 200	Celling Mounted	Operating Room	20
Neuro	Leica	OHC4	Ceiling Mounted	Operating Room	15
ENT	Zeiss	OPMI 1-FC	Floor Stand	Operating Room	25
ENT	Zeiss	S100 / OPMI PICO	Floor Stand	Operating Room	12
ENT	Zeiss	Stative S8	Floor Stand	Operating Room	23
ENT	Zeiss	OPMI Movena	Ceiling Mounted	ENT Clinic	12
ENT	Zeiss	OPMI Movena	Ceiling Mounted	ENT Clinic	12

Along with basic information, reviewing current conditions, capabilities and challenges of the existing equipment will be helpful to analyze the future equipment needs. In this regard, reading the brochures, discussing with vendors and users of the current equipment, in-person examination of equipment is all important for understanding the hospital's technical requirement.

2) Market analysis

The biomedical industry is constantly releasing new and impressive medical devices with many new features. A market analysis determines which manufacturers and products are available in the market. Many times, regular customers of brand companies are unaware of other possible solutions, so they may forgo the opportunity investigating the best option for replacement of their medical equipment.

Performing a proper market assessment is essential to ensuring a healthcare organization gets a fair and equitable price when replacing equipment, especially for high-cost and highly technical devices. ECRI (Emergency Care Research) can provide comprehensive information on medical equipment including a comparison chart of equipment specification of all manufacturers of medical devices. After contacting vendors that distribute surgical microscopes and consequently contacting them, a series of vendor meetings were set up to present the products in detail and provide brochures and pricing information related to the specific equipment. It would be helpful to request and schedule in-person demonstrations or high-level overviews on equipment, as they would help to further understand the new features offered in technologies and our requirements.

It is also necessary to discuss experience with the required technology with other peer institutions. One of the best ways to gather information is to survey their staff and conduct follow-up or supplementary interviews with selected staff members and individuals inside and outside the institution. Questions on the survey should cover the perceived adequacy of the current equipment, physician and clinical staff preferences and their rationale, estimates of the technology's impact on patient volume, and the equipment and systems needed to meet that volume. These testimonials will then need to be translated, as not all feedback will apply, to the needs of facility replacing the equipment.

In the case of surgical microscopes, a comparison list including all manufacturers of surgical microscopes was extracted from ECRI website. Carl Zeiss Meditec Inc and Leica Microsystems Inc are two German companies that manufacture surgical microscopes. Each company has a vendor who can distribute and sell in Canada. Each vendor was reached, and a series of in-depth meetings were arranged. In-person site visits were organized at Queensway Carleton, Focus Eye Center, The Ottawa Hospital Civic Campus, and The Ottawa Hospital General Campus so the vendors could demonstrate their advanced technologies and share information of recently installed surgical microscopes. Moreover, the vendors reported the number and location of installed microscopes in Ontario, and a survey was designed to receive feedback from pediatric and local hospitals on their current surgical microscopes and their vendor experiences (survey available in Appendix A). The survey consisted of 12 questions. Each participant was asked about their experience with their surgical microscope's technologies and their level of satisfaction with vendors. We also connected to The Ottawa Hospital Clinical engineering team, as they had recently purchased 8 surgical microscopes across 3 specialties from Leica and Zeiss companies. A meeting was set up, during which an overview of their work on procurement was given, and they provided their RFPs (Request For Proposal) on surgical microscopes

3) The identification of requirements

The identification of requirements generally focuses on replacing existing equipment or adopting proven technologies. It is an important process to provide end-users with the information needed to prioritize and select appropriate medical devices. Based on the configuration of existing technologies and what is available in the market, a list of the requirements must be created; they should be generic and non-vendor-specific to minimize bias [15].

Medical technology user involvement is essential to develop a reliable need analysis. Defining the lead clinician and staff members is important to ensure appropriate vetting of the needs analysis. Multiple meetings should be held to select required features. It is preferable to ask the end users to prioritize their needs and indicate which option of their future equipment is a “must-have” and which one is a “nice-to-have”. The must–have features have the highest positive impact on the ability to provide optimal services to the organization, while nice-to-have options are likely to have a high impact but will also demand substantial resources. For example, based on the discussion with ophthalmologists, an integrated camera is a Must-have feature, while a 3D Visualization is a nice-to-have option.

Not only the technical features of the equipment but also all requirements related to facility modification, information technology (IT) integrations, and any needed ancillary should be asked and identified before requesting the budget. Below is an illustration of this approach in the case of an ophthalmology microscope with investigative questions to extract clinical requirements [15].

1) Question: Are there installation limitations or requirements of existing equipment that need to be investigated before requesting for the budget (Is facility modification required)?

Answer: The clinical users of ophthalmology microscope requested to change the installation type of existing this microscope, and the CHEO facility team provided the specification for the new surgical microscope and estimated the costs involved in changing the installation type for this scope.

2) Question: Will the proposed equipment be utilized in conjunction with existing or future equipment in the facility?

Answer: In the case of the ophthalmology surgical microscope, they must have filters to protect the surgeons and the assistants from the 532nm laser if/when they do endoscopic laser. In a reported case, when surgeons bought a microscope, they forgot the laser filters, which rendered the laser unusable for endoscopic laser for 6 weeks until the filters were installed in the scope. The surgical microscope vendors do not supply these filters, but their purchase and installation must be included in the overall quote, even if they come from another supplier.

3) Question: Is the equipment required to be in the hospital network?

Answer: The Ophthalmology and Neurosurgeons requested to integrate the prospective surgical microscope into the Electronic Health Record (EHR) system. The cloud based EHR system for transferring patient information to the patient chart at CHEO is EPIC. The technical requirements for the integration were obtained from CHEO’s IT department.

4. *Cost Analysis*

The last step in this process is estimating the initial cost of the acquisition. This one is obvious, but worth mentioning, make sure to compare quotes from more than one vendor when looking for capital equipment!

The initial cost should include all cost items that need to be reflected in the budget that will be requested in capital planning submission. It is concluded as a proper way to make reliable estimations. Below is what should be included in the initial Cost for Acquisition:

1) *Unit Price and quantity*
2) *Facilities installation / modification / renovation cost*
3) *IS equipment, installation, network & integration cost*
4) *Maintenance & service training cost*
5) *Any other related cost*

If other departments need to contribute to the project but have not been identified, it could result in the project not being approved or a delay to future years. The best process to assemble this information is to gain input through a series of meetings with related departments.

Moreover, some hospitals have a multiyear capital equipment plan. So, the submitted budget request should estimate the prices considering the possible contingencies until the budget is allocated.

The aforementioned steps were followed up and the requirement and configuration of new surgical microscope were identified, and the total cost was estimated based on the requirement. The table below shows the total acquisition cost of an ophthalmology microscope for budget planning:

TABLE 2
TOTAL ACQUISITION COST OF AN OPHTHALMOLOGY MICROSCOPE

Unit cost: An ophthalmology Microscope	According to a quote from a vendor in September 2022, the price of one Ophthalmology microscope with required features is $800,000.00
Integration cost	The software/integration cost estimated by the Information Service team is $20,000
Installation cost	The installation cost which included replacing the current ceiling mounted ophthalmology microscope with a floor stand microscope is $20,000
Maintenance and service training costs	All surgical microscopes come with a one-year comprehensive warranty on spare parts, labor, travel time and repair. After the warranty period, the hospital can decide to either send a technician for training to do all the preventative maintenance in-house or sign a service contract for each scope. Service contract for the Ophthalmology microscope is $48,000 The training course is $5,000
Total cost of acquisition:	+/- $840,000.00

IV. CONCLUSION

It is important to replace old and obsolete technology with cost-effective and advanced ones to maximize the value of the healthcare system. There are different factors impacting a medical equipment replacement decision that needs to be thoroughly investigated to have a prioritized list of equipment, preventing immediate and unbudgeted replacement of any medical devices.

One of the key successes of strategic capital planning is having an approved budget which reflects the best estimate of the medical equipment for the procurement time. This requires careful consideration before requesting the budget. The more clinical specifics and requirements identified, the more accurate and manageable the cost estimate. For example, a cost estimate for a 3D ophthalmology microscope based on a discussion with the clinical staff is more exact and advisable than simply estimating an ophthalmology microscope, leading to the purchase of a more functional device.

Moreover, the calculated cost should include not only the acquisition cost but also the costs related to relocation and installation, information technology (IT) integrations, and other expenses for ancillary. Significant gap between the required budget based on what the users identify as requirements for meeting clinical goals and the approved budget may signal a problem.

This project was carried out to investigate the requirement for future surgical microscopes based on CHEO needs and estimate the total cost of the project for budgetary planning purposes through a step-by-step methodology. The example of an ophthalmology surgical microscope was provided as a guide.

V. FUTURE WORK

Based on the budgetary pricing received from each vendor, the acquisition costs for each modality were calculated and a capital request has been submitted for funding. Once the budget is approved, the procurement process will be started. The information in this report can be used in the procurement of surgical microscopes. A formal Request For Proposal (RFP) will be written and posted for each specialty. Once a multidisciplinary team has selected which vendors will be considered, the vendor trials can start. Members of the multidisciplinary team then will be able to trial the equipment, ask questions, and evaluate and rank each vendor. In addition to clinical usability and patient safety aspects, it is essential to examine the devices from the perspectives of infection control and cleaning, accessories, supply, clinical training, technical training, and serviceability. Based on the market analysis in this report, more than one vendor would be able to fulfill the needs, making it necessary to conduct more research about each vendor. Therefore, vendor reliability and customer service, life cycle cost analysis, and warranty will be considered along with other requirements to select a vendor which best suits our needs.

APPENDIX

Appendix A: Surgical Microscope Survey:

CHEO

Surgical Microscope Survey 2022

Specialty, Company (Make and Model):

Your position or title:

Number of times used:

This survey collects opinions and observations from Clinical users who have worked with a surgical microscope.

Questions:

1. What is your history with this vendor?

2. Would you buy the system from the vendor again?

3. What is your turn around time on repairs?

4. What is your feedback on clinical training and support? Can you get them on the call A.S.A.P.?

5. How have you found the operation? Ease of use?

6. Have you had issue or incident where the user is confused by the system?

7. Have you had issue with draping the microscope?

8. Have you had issues with balancing the microscope?

9. What is your feedback on Service?

10. What is your feedback on Service Training?

11. Overall, what is your impression/advice/recommendation with this vendor?

12. Are there any other issues we should know about concerning your experience with this vendor?

Any additional comment:

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