The ethical allocation of scarce resources in surgery: implants and cost

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This paper is a discussion of the factors involved in instituting a bulk purchasing program for surgical supplies. An improved understanding of the surgical procedure of joint arthroplasty must relate to the variability in surgical methods that achieve patient outcomes. An understanding of the outcomes in relation to the expected duration of the success of an implant and the high costs associated with a revision earlier than expected must be factored into the budget and costs of implants. The ethical implications of choosing one implant over another are considered. A more uniform outcome assessment with respect to surgical activities is needed and potential savings related to other operating-room costs must be examined. Optimizing the implant to patient requirements is the goal within the framework of current fiscal constraints.

On examine dans ce document les éléments qui entrent en jeu dans la mise sur pied d'un programme d'achat en vrac de fournitures chirurgicales. Pour mieux comprendre la procédure chirurgicale dite arthroplastie des articulations, il faut tenir compte des diverses méthodes chirurgicales qui donnent des résultats chez les patients. La durée prévue de la période de non rejet d'un implant et les coûts élevés liés à l'examen plus tôt que prévu doivent être pris en compte dans l'établissement du budget et du coût des implants. On examine également les considérations d'ordre éthique liées au choix d'un implant plutôt que d'un autre. Il convient de procéder à un examen plus uniforme des résultats des interventions chirurgicales et d'évaluer les économies éventuelles sur le plan des autres coûts de la salle d'opération. L'optimisation de l'implant par rapport aux besoins du patient est l'objectif visé qui s'inscrit dans le cadre des restrictions financières actuelles.

In the current financial climate, many hospitals have taken to stringent cost-cutting to balance the books and provide acceptable levels of care. Surgical services have been especially targeted because much of their work is classified as "elective" and is seen as eminently modifiable according to the financial dictates of the hospital administration. Although surgeons generally have cut bed days, increased same-day admissions and moved more to outpatient surgery, surgical costs are still the subject of intense scrutiny in all hospital administrations. The reasons for this include: a better ability to identify and cost surgical supplies in a generally poor accounting structure; a desire to achieve further cost savings based on a history of decreased bed availability not resulting in a measurable decline in standards; a desire to "tame" a group of professionals perceived to be more concerned with volume and income than medical services; and a continuing belief that "elective" surgical procedures are not as important for the general health of the population as more urgent events, like treatment for pneumonia and myocardial infarction (although data recently published would indicate that Canadian patients are not doing as well as American patients).[1]

All surgeons using identifiable supplies, whether sutures, stomach staples or protheses, are now being asked to standardize their use and participate

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in bulk or volume buying to lower the unit cost. There are some inherent dangers in this approach if the exercise is reduced purely to the cost per unit and is not seen in a wider context.

Surgeons' techniques

Surgical procedures must be seen as more than isolated acts in a continuity of patient care. Each surgical procedure may share goals or have goals defined in terms of outcome, but these outcomes are not just dependent on the surgical procedure, nor are all surgical procedures performed in the same manner to achieve the same result. The interaction between the patient and surgeon is well recognized for its prognostic importance. It must also be recognized that surgeons approach each operation differently and use techniques best suited to themselves. These techniques are the result of training, in residencies or fellowships, or later during continuing medical education (CME) events and career development. It is possible to examine outcomes formally, through clinical trials, and informally, through quality assurance programs. These outcomes determine the success of a surgeon's technique, but it is difficult to isolate those aspects of technique and directly attribute them to outcomes. For example, analysis of total knee replacement using a critical path methodology revealed that for the operation of a total knee replacement using one particular instrumentation system, there were 42 steps.[2] A certain number were graded as critical, according to the number of revisions of those steps. Individual surgeons would modify the number and order of those steps in a manner unique to themselves. Surgeons need to be trained and able to achieve the outcomes of total knee arthroplasty using the instrumentation and techniques best fitted to them. With a larger number of product supplies available, it is easy for individual surgeons to select those implants whose instrumentation and performance characteristics best suit them. Bulk buying prevents this process, and another major danger presents itself: patients presenting for a particular procedure, for example joint arthroplasty, are heterogeneous, and not all will be satisfied with a particular implant. It is necessary for the surgeon to choose the implant that best suits the individual patient's characteristics.[3]

Outcomes

Outcomes of operations can be categorical (life/death) or continuous: survival curves of joint arthroplasty, weight loss maintained over time after gastroplasty or improved quality of life after open or laparoscopic cholecystectomy. It is much easier to measure categorical events, and far more difficult to measure continuous, longer term events. It is expensive and time-consuming to assemble and track a cohort of patients after any intervention. If surgeons are unable to follow up their patients over time in an appropriate scientific manner, then the performance of implants or devices cannot be properly monitored. In Canada and the United States, individual centres or surgeons have been responsible for maintaining and reporting on databases of their results of hip and knee joint arthroplasty. In Scandinavia this function is performed by government and institution-sponsored national registries of hip and knee joint arthroplasties.[4] In Canada and the US individual prosthetic supply companies have often sponsored this activity, and this cost is included in the purchase price of the implant. If that cost is factored out of the implant cost, it must be factored in somewhere else in the hospital budget. It cannot be dropped expediently to balance an operating-room budget. This is of particular significance in orthopedic surgery where implants are designed to last for 10 years, and a poor result at 5 years after operation results in a far heavier cost to the hospital and society for revision of the failed implant. The surgeon has to live with those results whereas the administrator responsible for the institution of bulk buying may have moved on to another job. It is the responsibility of the surgeon to manage the patients' complaints in relation to any waiting list and in relation to the patients' expectations from the proposed surgery. Surgeons are already matching implant designs to patients' demand levels, and there are at least 2 industry-sponsored trials addressing this in knee arthroplasty.

Ethical considerations

There is an ethical issue with respect to marketing and promotion of devices and procedures that has been well addressed for the orthopedic surgeons of Canada by the Ethics Committee of the Canadian Association of Orthopaedic Surgeons (COA).[5] There has to be training of surgeons for the use of new implants or procedures. This is a recognized CME activity. There have to be guidelines for industry and surgeons relating to the appropriateness of the training as well as the marketing of devices, and as the COA suggests this is a matter for individual examination within a broad framework of recommendations. A well-trained surgeon who is ethically aware and acting in the best interests of the patient will use the equipment appropriately, in the expectation of obtaining a good result for the patient. A well-designed scientific trial is the best marketing tool a supply company

could wish for. Implicit in this is the ability of the company to appropriately train the surgeon, whether by video, laboratory simulation or visits to another surgeon or facility. This all costs money and is a part of the cost of any implant or device used.

Discussion

An understanding of the complexities and the interactions of these 3 areas, namely the surgeons' techniques, outcomes and ethical considerations, in the choice of prosthesis is a prerequisite for all participants in a bulk purchasing scheme. The proposed financial savings often discount the issues of training and evaluation and leave surgeon, patient and hospital at a disadvantage with respect to patient outcome. Although the surgeon continues to bear the responsibility for the outcomes of surgical procedures, the surgeons themselves must be allowed to determine what is necessary for them in order to learn new techniques and accurately document the outcome of their interventions. Hospitals must recognize that this form of outcome assessment is integral to the practice of surgery. It may be seen as a form of quality assurance independent of the usual hospital-sponsored quality ssurance programs.[6] In general the cost benefits of this current methodology favour the hospitals. To change or deny the ongoing education, evaluation and long-term outcome analyses will not benefit the Canadian public.

The amount of savings that can be realized through bulk purchasing of prostheses must be judged in the context of the total costs of the operating-room budget. Often surgeons are given the "missing value" spreadsheet when making judgements regarding costs. For example, the majority item on most operating-room budgets is salary compensation. Employees who are chronically absent from work must be paid for and replaced. These costs are substantial; they are hard to get and are not given to medical staff. In our institution it took me 4 weeks to identify the costs with respect to staff on long-term disability. The replacement costs are estimates, the actual figures are not formally collected, but were estimated to be $129 800 for 1 operating-room unit for 1 year. This sum is considerably more than any bulk-purchase savings. Similar figures for laundry versus disposables and day patient versus same-day admissions are required for surgeons to make a value judgement of the proposed savings in their areas of expertise. Often the complete picture is not even presented to the operating-room committee. The savings achieved by same-day admissions and early discharge are not credited to the operating-room budget, even though the more efficient use of beds often results in increased pressure on the operating room by allowing more procedures to be performed.

If we consider the ethics of the allocation of scarce resources — surgical implants — then the surgeon must be seen to be acting in the patient's best interests. Using a cheaper implant but getting poorer results is not ethical. Using an implant with which the surgeon has no experience, either through trials or self-assessment, is also not ethical. If the choice is fewer expensive implants versus more cheap ones, the surgeon who makes that decision must act for the benefit of the patient receiving the implant. Doing more surgical procedures to maintain an income is unethical, yet this is the "carrot and stick" approach often used in discussion with administrative staff. The surgeon is responsible for the choice of implant and the consequences of that choice. It is unethical for a surgeon to use a new prosthesis or implant without setting in place an appropriate mechanism for collecting data on the outcome of its use. Risk-management strategies would focus on the outcome of those choices and how those data are given back to the surgeon to modify the choice.

Surgeons and their representatives have a clear ethical decision to act in their patients' best interests, to explore outcomes in an appropriate way and to demand a complete financial summary when allocating the scarce resources of the operating room.

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