Major medical instrumentation procurement and maintenance

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Abstract

The procurement of major medical instrumentation such as x-ray units, CTs, MRIs, large lab instrumentation, physiological monitoring, or operating room equipment requires planning. The first step is for the hospital to decide if this technology is needed. In the case of replacement, a decision should be made on the necessity of replacement - not functioning, obsolete, or newer technology required. A decision to procure the major medical instrumentation should be from the recommendation of a technology committee. This committee should include administration, medical staff, nursing staff, clinical engineering and facility engineering. The decision should be based on healthcare delivery need, availability of users, and cost to procure, install, and maintain. The engineering staff is critical to assure that space and utilities are available and a maintenance plan is developed. Specifications should be developed for bidding or other procurement process. These specifications must include compatibility with other equipment, training required for users and maintenance staff, operating and maintenance manuals. If there is diagnostic software, specify that the maintenance staff have access. Considerations must be made for the infrastructure and infection control with the usage. Is the equipment going to be tied into the hospital network for data processing and display? Once the equipment is installed, it has to be maintained by the clinical engineering staff or by maintenance contracts that they monitor. This staff may need to be trained by the manufacturer for the level of maintenance that they will provide. The clinical engineering staff should also attend the user training so they will know how the equipment functions.

Selection

First step in the procurement of any major instrumentation is the selection process; and the first step in the selection is to determine what instrumentation is needed. This is a major part of the planning process for procurement. Several factors must be considered and they can be divided into organizational factors, human factors, technological factors and economic factors.

The organizational factors take into account the need for the organization and this requires adequate planning by the organization. One of the first issues that must be considered is the utilization of the instrumentation that is going to be purchased. This is especially true for new instrumentation and not just a replacement. The other thing that must be considered is how does this equipment integrate and coordinate with existing systems. Someone has to review the equipment that will interact with this instrumentation for the whole organization.

Human factors primarily involve the staff. Do they have an adequate understanding of the role and the technology of the equipment? How will it improve patient care? Sometimes staff will have a resistance to innovation and change and as a result, resistance to new instrumentation. Another human factor is the impact of this new instrumentation on the traditional delivery methods. Will this new instrumentation do away with some procedures or other instrumentation that the staff is currently utilizing?

Technological factors must be considered when the instrument to be purchased is a new technology or at the cutting edge of existing technology. People will ask, is the instrumentation simply a tool or does it threaten a caregiver's job? By utilising this new instrumentation, is less staff needed or is different staff needed? There should be transparency and connectivity with existing systems. This new instrumentation should fit with other equipment and this must be looked at very closely. The functionality of the instrumentation must be considered. People need to be sure that it has relevance and usefulness, not that it is just a nice piece of equipment to have and doesn't really do any more than existing equipment. The technology factors that need to be evaluated closely by the selection committee are the real and perceived attributes. Will the equipment have the desired features? Will it be user friendly? Is it simple to operate? Reliability is a major concern with technology. How reliable is it? How easy is it to maintain? Can it be updated easily? These are questions that the selection committee must ask and determine that the answers are real and not just perceived attributes of the instrumentation.

Economic factors need to be considered. Unfortunately, administrative people frequently start with the economic factors and on the other hand, the clinical staff may ignore the economic factors. Economic factors are very encompassing. What is the cost to acquire the instrumentation? That is pretty simple. Some people will stop at that point, but there is a cost of implementing or adopting new instrumentation or even replacing instrumentation. If it is new instrumentation, there is an additional cost to maintain it. The cost benefits to the organization need to be considered. What are the cost benefits to the hospital to have this replaced instrumentation or new technology available? If this is additional instrumentation, there should be a comparison between the cost benefits of existing similar instrumentation and this proposed acquisition. Economic factors need to take into

account a projection of the usage of the instrumentation. One might consider whether or not it would be better to develop a sharing agreement with another hospital that already has this instrumentation as opposed to purchasing the instrumentation and then being responsible for the full operating costs.

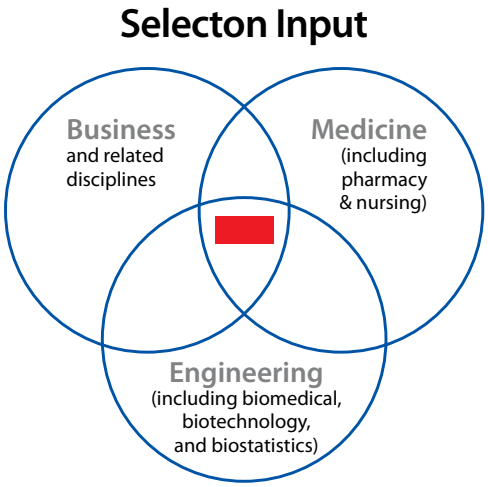

Figure 1: Selection Factors Input

It is not possible for one person to address all of these factors. Figure 1 shows the input that is required. There needs to be medical input which could include pharmacy, nursing and other medical staff involved in the use of the major medical instrumentation. There is engineering input, with regard to the technology, maintenance and whether there is space for it. And then there is the business input which will look at the economic factors. Therefore, a committee is required which will include hospital administrative staff, including the chief financial officer, medical staff including a physician, nurse and other allied health as required, engineering staff which should include the hospital engineer and a biomedical engineer.

Once a decision has been made on the instrumentation needed, there needs to be an evaluation at where the technology of the instrumentation is on the lifetime curve of technology? Figure 2 shows a technology lifetime curve from the innovation of a new technology or instrumentation to the development of a prototype and then the application. A medical center would not want to select instrumentation on the downhill side where it is becoming obsolete. The best time for selection would be near the peak as it is being incorporated. This would provide for the longest useful lifetime of the instrumentation as well as the availability of parts and maintenance. The life cycle of the instrumentation is not a definite fixed timeframe. In fact, the manufacturer cannot guarantee the life cycle of the equipment especially since they do not make all of the components. An example at one hospital was that they purchased a Siemens computer radiology unit in 1994 with a contract for parts to be available for 10 years. In 1998, the primary interface card was no longer made or available from the vendor, which was 3 COM. In 1999, no replacements were available anywhere. In 2000, Siemens could do a re-design and retrofit at a cost of $30,000. The question now becomes, should one wait for Siemens to design a fix and pay that money, should one sue Siemens, or should one replace the equipment?

As one looks at procurement, several factors in addition to the purchase price must be considered. A life cycle cost needs

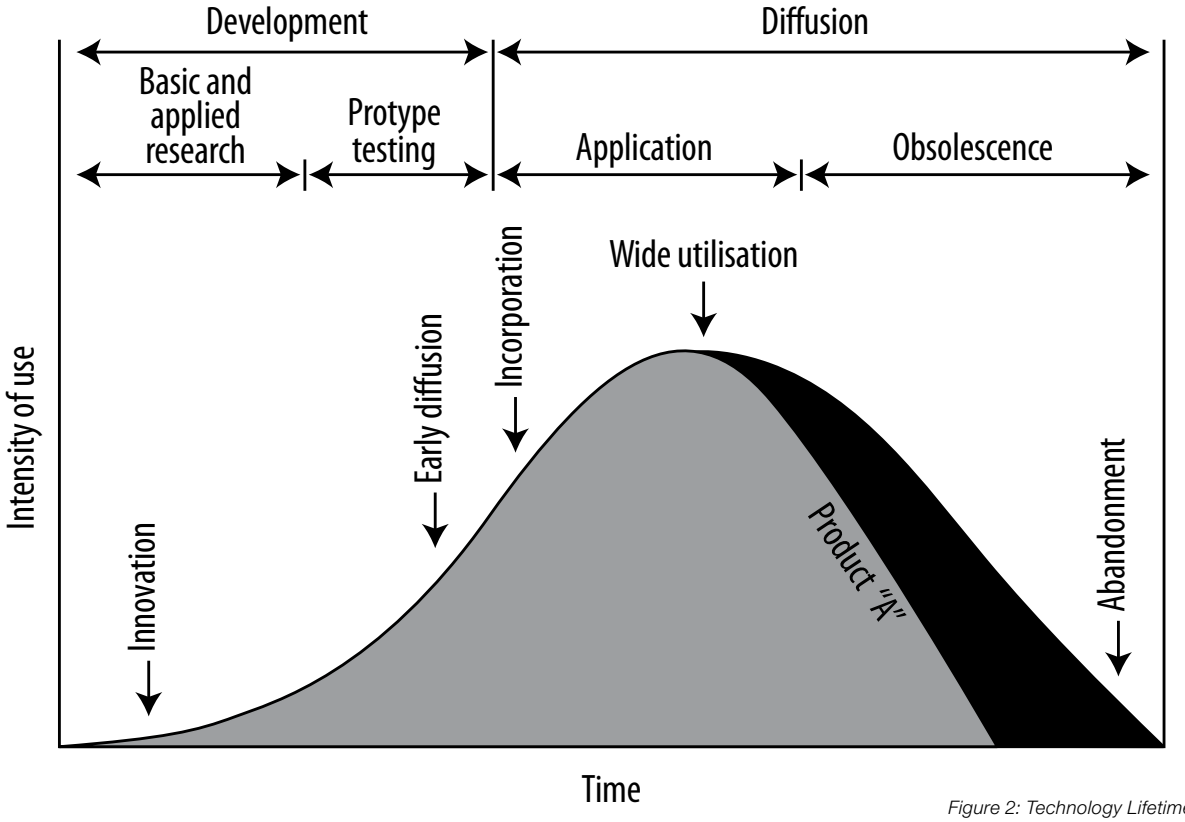

Figure 2: Technology Lifetime Cycle

to be looked at, which includes price of the instrumentation, the cost to install, the cost to operate, the cost to train staff, maintenance, and a support cost including the utilities. This is shown in the iceberg effect in Figure 3. Like an iceberg, the purchase cost is only about 10% of the cost of owning a piece of instrumentation over its lifetime. Very often, instrumentation is purchased without taking all of these factors into consideration. The cheapest purchase price is frequently considered when if one looks at the life cycle cost that may well be the most expensive total cost.

Acquisition

After the selection, the next step in the procurement process is the acquisition. There are several different methods of acquisition that can be used, but there may be some limitations depending on the source of the funds. The bid/tender process is probably the most common and is usually required for government agencies and international loans. This process offers the best opportunity for fair competition, but it is lengthy and bureaucratic. The bidders can be limited by using a request for proposals (RFPs) to determine qualified bidders. The RFP should include the technical specifications and life-cycle costs, operator and maintenance documentation, training, performance bond and penalties. All of these items need to be included in any acquisition process.

The next acquisition method is direct purchase from the manufacturer or distributor. This method allows for standardization of devices, is less bureaucratic, and specifications and requirements can be changed during the purchase process. The disadvantage is that there can be biases toward a vendor due to a long-term relationship. If this is a good relationship, this can also be an advantage.

A group purchasing organization is another method of acquisition. This is where several hospitals are buying together to gain volume discount. One organization negotiates with all suppliers. This method is common in the United States, with hospital organizations, group purchasing organizations and the United States government agencies. The advantages of this method are cost savings, good support and training and information readily available. The disadvantages are potential high membership costs and inflexibility in standardized products. The Department of Veterans Affairs negotiates contracts for major medical equipment on three-year contracts. Sometimes there are contracts with more than one vendor for similar systems such as x-ray units. The Department of Defense also purchases from these contracts.

There are acquisition alternatives to purchasing including lease/rental and supplies/reagents commitment agreements. The lease/rental requires no initial investment and the hospital only pays for the period of usage. However, there is usually a minimum lease/rental time period. Updates and upgrades come as part of the lease/rental. With a rental there is no maintenance, but on a lease the maintenance may be the responsibility of the hospital. Some instrumentation may be leased to own, which usually requires a balloon payment at the end of the lease. There is a higher total cost for a lease/rental over the lifetime of the equipment, but no capital improvement funds are involved. The supplies/reagents commitment agreements are common for clinical lab and

Iceberg Effect

Purchasing Cost

After Purchase Costs

Transport and installation
Operating
Staff
Training
Maintenance
Recording and Evaluating Data
Supplies
Administration
Removal and Disposal

Figure 3: Purchasing Iceberg Effect

dialysis where a large quantity of supplies and reagents are used. These agreements cover all other costs of the equipment and maintenance. The main disadvantage is that they require a minimum order for supplies and reagents.

Engineering Implications

During procurement of any medical instrumentation, there are implications for the healthcare engineering staff. This includes the hospital engineering personnel and the biomedical engineering personnel. One of the first implications is the installation. The engineering staff must be sure that space is available for the equipment, utilities are available, and consideration has been given for maintenance. In some hospitals, there is a requirement that any purchase for medical instrumentation requires a signoff by the hospital engineer to assure that space and utilities are available. This assures that they will know that the equipment is being purchased and have that space and utilities available when it arrives. If this is a replacement, there is a requirement for the removal of existing equipment.

Biomedical engineering staff is generally involved in patient safety to assure that the equipment will be safe for the patients. This may be for electrical safety or for mechanical safety depending on the instrumentation. They are generally responsible for being sure that the instrumentation meets all of the various standards that are required. This is especially critical where instrumentation may be purchased from one country to be installed in another country.

For major medical instrumentation, there are several installation implications that have to be considered. With most equipment, information technology interactions must be considered. This may involve how it is going to interact with the hospital information system. Is adequate bandwidth available? What are the utility requirements? Is adequate power available and does the equipment need to be on the emergency power system. If there is a power outage, they need to be sure that adequate emergency power is available to support the equipment. A lot of medical instrumentation requires air conditioning and ventilation therefore the HVAC must be considered. If the installation requires major infrastructure changes, there needs to be consideration for fire protection and infection control during the changes.

There is a lot of information going between medical instrumentation, being analyzed, and put in the patient's records so the overall environment of information has to be considered. One factor that has to be considered, does the hospital have one information system? Is information from the major equipment, such as, radiological systems going to be on the same network backbone as the hospital information system? This is the preferred method so that all data can be put together on a patient record at some point.

Maintenance

Engineering then has to worry about the operation of equipment. At the point of installation, they should have assured that appropriate utilities are available including emergency power.

But these have to be checked periodically and maintained appropriately. The maintenance of the instrumentation is a function of biomedical engineering. This can be handled in different ways. The main issue with the maintenance is the performance of the instrumentation to be sure that it is functioning reliably and that the data provided is accurate. The maintenance program has to assure that the instrumentation is repaired in a timely manner whether this is by in-house staff or on a contractual basis. With most major medical instrumentation, part of the maintenance is accomplished with some type of contract. This can vary from a full service contract including preventative maintenance and all repair maintenance to a contract that guarantees on-call maintenance or parts. A frequent contract is a reduced maintenance contract where in-house staff will take the first look at the equipment to be sure that it has power and that all of the settings are appropriate. They will talk to the company service staff and may be told how to perform tests and make some repairs. If that does not fix the problem, then the company will send in their service people but at that point, they have a good idea of what the problem is. They know what level of staff is needed as well as what parts they might need. In all cases, the biomedical engineering staff must maintain the records of the maintenance. They should be knowledgeable of the maintenance that is performed and when it has been performed. In fact, they should have a copy of all service records on the equipment. In most hospitals, there is a requirement that any service personnel come through the engineering department and leave through the engineering department, leaving documentation of the maintenance that was done.

Managing the service contracts can be very cost effective. The contract manager will assure that the service contracts are appropriately written for the timing of service that is needed. Contracts should not be written for 24 hours a day, seven days a week, service unless that is required. They will assure that the service personnel perform the service that they say they perform. In many cases, as they monitor the service, they can determine that the same repairs are being charged for and if a symptom is being treated rather than the problem being fixed.

Maintenance schemes in the medical field are changing. Some of the schemes that are being used in the space program and in the aeronautical industry are being considered in healthcare facilities. People are looking at doing predictive maintenance and reliability centered maintenance rather than doing the kind of maintenance that has been done forever. This maintenance makes a change in how much preventive maintenance is done. In some cases with the high reliability of electronics, one can talk about mean time between failures in the order of years. There may be no preventative maintenance done especially after a risk analysis is done for a failure. Some studies have been done that show that preventative maintenance may cause more problems than it solves with the current technology.

Reliability centered maintenance is a logical, structured framework for determining the optimum mix of applicable and effective maintenance activities needed to sustain the desired level of operational reliability of systems and equipment while ensuring their safe and economical operation and support. Reliability centered maintenance focuses on identifying preventive maintenance actions, corrective actions are identified by default. The reliability centered maintenance approach provides a logical way of determining if preventive maintenance makes sense for given equipment and, if so, selecting the appropriate type of preventive maintenance. When no preventive action is effective or applicable for a given item, then that item is run to failure assuming safety or a similarly critical consideration is not an issue.

Training of the staff is part of the program for maintenance of medical equipment. The clinical staff must be adequately trained to use the equipment appropriately so that there are no operator errors. The clinical engineering staff, both engineers and technicians, need to be trained on the equipment operation the same as most operators. They also need to be trained to maintain the equipment. Maintenance training needs to be at a level that they can do first call service or monitor the service contracts. In many cases, generic training on equipment such as x-ray systems is adequate for this level of training. If they are to do full maintenance coverage, they need to be trained by the manufacturer.

Whenever possible, technicians should be certified. This will assure that they have a certain level of competence. This does not mean that they need to be certified on how to maintain each specific piece of equipment. They need to have a general certification so that they will know the concepts for operating equipment, they will understand the language of the medical staff, and have an adequate electronics background that they can read manuals and troubleshoot the equipment. The certification of technicians does not guarantee a better level of maintenance. It does guarantee a certain level of confidence which is especially important if the technicians are not graduates of a known training program.

At the end of the life of the equipment, there has to be a replacement or disposal. Basically at this point the process starts over. After the selection of new equipment, there has to be a disposal of the existing equipment. There needs to be an assurance that this disposal does not delay the installation of the new equipment. This is one reason that all procurements should go through engineering for a signoff to be sure that they are aware of what has to be done and when it has to be done. As part of the disposal the existing equipment might be sold to a medical center that doesn't require as high a level of technology, it may be traded in to the vendor, it could be donated to a hospital that doesn't require as high a level technology especially in a developing country, or it may be cannibalized for parts.

The hospital engineering and especially the clinical engineers and clinical engineering technicians are critical to a good procurement of major medical instrumentation and the maintenance of it during its life cycle.

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