

Procurement of medical equipment in Sweden

Nabavljanje medicinske opreme na Švedskem

Heikki Terio

*Department of
Biomedical Engineering,
Karolinska University
Hospital, Huddinge,
Stockholm, Sweden*

Korespondenca/ Correspondence:

Heikki Terio, Ph.D.
Department of
Biomedical Engineering
Karolinska University
Hospital, Huddinge,
MTA C2:44
SE-141 86 Stockholm,
Sweden

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Abstract

In many hospitals in Sweden the importance of technology management is already accepted and accepted since the hospital managements have recognised that technology is an integral part of all major policy and planning decisions. Today's medical devices are technically complex and sometimes a system of interacting devices is required to achieve the desired clinical function. If the hospitals want to use the latest, modern technology, then they need to make substantial investments in both equipment and competence. Complex technology, large investments and need of highly qualified personnel to handle the medical devices are factors that indicate a need of well-defined procurement process as an essential part of the total health technology management system that should be used in a hospital. In such a procurement process, carefully prepared planning of technology investments can reduce the running costs and costs for maintenance substantially. In addition, a well-defined procurement process contributes to increase the patient safety. In Karolinska University Hospital goods and services are purchased for more than 20% of the hospital's €1.2 billion turnover. It is therefore very important that the procurement is carried out effectively.

Izvleček

V mnogih švedskih bolnišnicah so že spoznali, kako pomemben je tehnološki menedžment in to tudi sprejeli v praksi. Uprave bolnišnic so namreč ugotovile, da je tehnologija sestavni del vseh njihovih pomembnejših političnih in planskih odločitev. Sodobne medicinske naprave so namreč tehnično kompleksne; da bi dosegli njihovo želeno klinično funkcijo, je včasih potrebno vzpostaviti sistem medsebojno delujočih naprav. Če želijo bolnišnice uporabljati najnovejšo sodobno tehnologijo, morajo veliko investirati tako v opremo kot v usposobljenost osebja. Dejavniki, ki kažejo na nujnost, da se dobro opredeli sam postopek nabave kot bistven sestavni del celovitega sistema za celotno tehnološko upravljanje v bolnišnicah, so: kompleksna tehnologija, velike investicije in potreba po visoko usposobljenem osebju, ki bo kos rokovanju z medicinskimi napravami. S takim postopkom nabave lahko skrbno pripravljeno načrtovanje tehnoloških investicij bistveno zniža tako tekoče stroške kot stroške vzdrževanja. Poleg tega pa dobro opredeljen postopek nabave prispeva k večji varnosti bolnikov. V švedski Univerzitetni bolnišnici Karolinska obsega nabava blaga in storitev več kot 20 % celotnega prometa bolnišnice, ki znaša 1,2 milijarde EUR letno. Zato je tako pomembno, da se nabava izvaja učinkovito.

1. Introduction

Swedish healthcare system is decentralised into 18 County Councils, 2 regions and 290 local authorities that have autonomous taxation rights to finance and provide most of the healthcare services, only a small portion is financed by various types of insurances. The Swedish healthcare consumes almost one tenth of society's total resources and in 2007, the healthcare costs per citizen were \$ 3323 (adjusted for purchasing power parity) according to OECD Health Data 2009. Healthcare costs in Sweden rose as a percentage of the Gross Domestic Product from 8.3 in 1987 to 9.1 percent in 2007.¹

Economic crisis lead to demand for cost reduction and restructuring, which is often experienced as something very negative. However, it is apparent that restructuring is not only a matter of saving money but it can also be seen as a step to modernising the sector in question and it demonstrates the ability of the sector to invest and take advantage of new technologies. By exploiting technological advances in medicine, successful healthcare systems can provide their services in a more effective manner. However, improvement based on technological advances requires optimal use and handling of medical equipment. This optimisation includes not only good management of the existing medical equipment, but also planned investments of new equipment in order to replace old ones or to purchase completely new technologies to introduce new diagnostic or treatment methods.

The County of Stockholm is often described as the growth engine of great significance to Sweden and it accounts for a considerable part of the R&D work in the country. Stockholm County consists of 26 municipalities and has 2 million inhabitants, which is 21 per cent of Sweden's population. There are 7 major emergency hospitals in Stockholm, out of which one is private, but working for the County Council.

Karolinska University Hospital (Karolinska) is the largest hospital in Stockholm and it is also one of Scandinavia's premier health facilities. It has about 15000 employees, a €1.2 billion turnover and represents about

one-third of Stockholm County Council's resources on healthcare. The health services are organized into seven divisions that consist of 66 departments. Research and education are under a separate organization, but closely linked to patient care. A modern logistics and materials management system enables the hospital to use the same purchasing model throughout the hospital. In 2008, €33.6 million was reserved for investments in medical equipment and the 2009 budget for equipment investments is €34.3 million. The re-investment value of the medical equipment, i.e. how much it would cost to replace all the equipment, is €102 million.

2. Investment strategies

In order to meet the demands of modern, well-structured and cost-effective healthcare, Stockholm County Council is facing very large investments in the coming years, which will bring about a large increase in the County Council's capital costs. In the spring 2006, the County council therefore decided to develop a long-term strategy for the investments, which includes a proposal for a new priority model for investments and a survey of investment needs for the period 2006 to 2030. This includes a calculation of the investment frame for the corresponding period. The general healthcare sector development such as the development of medical methods and technologies were considered when working with the strategy.

There are four types of investments with different objectives and these different investments need to be addressed in different ways. The purpose of the investment determines the processing rules (calculations, etc.) to be applied in the preparation of a given investment project. The first type, strategic investments, is made up of investments with the primary objective to implement structural changes in the healthcare system and greatly increase the ambition vis-à-vis the citizens in the County. The second type, local new investments, are by their very nature quite similar to the "strategic investments", since these normally also are relating to an increased ambition level. The local new investment has the primary objective, as the

name implies, to increase ambition level locally, for example to meet new demands from the authorities or the political leadership. Management of medical technologies also includes the follow-up of the equipment's condition and planning for the replacement of old and out-of-date devices. Therefore, the third type, re-investments, is the most common type of investments and often demands a significant amount of capital. Re-investments are made to ensure and maintain the current level of services and/or to update the technical solutions used for the operations. The fourth and the last type, rationalisation investments, consists of investments with the primary objective to achieve increased cost efficiency without compromising the ambitions towards the citizens of the County. For assessment of these rationalisation investments, a cost-benefit analysis should be done in accordance with the principles of business economics.

3. Procurement process

Carefully prepared planning of technology investments can reduce the running costs and costs for maintenance substantially. In addition, our experience shows that it also contributes to increased patient safety. A well-defined procurement process is an essential part of the total management system that is used at the hospital. The procurement process at Karolinska applies to investment in all goods and services, however this presentation deals only with medical equipment.

The procurement process of Karolinska has been developed in accordance with the County Council investments strategies and the process has to be used by all departments and divisions of the hospital when purchasing, leasing or renting medical equipment. The hospital is subject to the European Union Act on Public Procurement, which is the basis for how procurement must be carried out and applies generally to all EU countries. The objective of the Act is to ensure that procurements are made in a professional manner and with competition. No company shall be discriminated and all vendors must be treated equally. Furthermore, procurements shall be carried out transparently so

that all vendors who have products that meet the tender requirements, must be given the opportunity to make tenders. Karolinska is environmentally certified according to ISO 14001:2004. Therefore, the hospital is also obligated to conduct the procurement in accordance with the hospital's environmental policy and the County Council's environmental programmes.

The hospital procurement policy states that all procurements shall be carried out so that the hospital's operations will get the goods and services with the required functions, adequate quality and high-security at the lowest possible cost. In the hospital it is the Purchasing Department (PD) that is responsible for optimizing the procurement process function linked to the procurement process, but all procurements shall be carried out in close co-operation with the representatives from the departments where the equipment or services are needed. Coordination of different investment projects within the hospital and even within the Stockholm County Council shall be considered preferable since large volumes generally result in better purchase prices.

The procurement process is initiated when the hospital starts to work on the investment plan for the next year. The departments will make an inventory for equipment with an investment cost of over €100,000. For equipment under that amount the divisions will get a lump sum for the budget year, and planning and decisions are thereafter made by the division management, but otherwise the process is the same. When demanding new investments, the departments have to carefully explain why they need the equipment and what is the degree of priority to purchase it. Further to this, they also have to specify which of the four types mentioned above the investment belongs to. The inventory lists from different departments of one division are compiled and different purchase objects are given priority with regard to the division's short- and long-term goals. Thereafter, the investment proposals from all divisions are compiled once more by the hospital's investment board, consisting of persons with different competencies for investment assessment. The investment board

Figure 1: A schematic illustration of the procurement process dealing with the purchasing of goods and services at Karolinska University Hospital.



has to keep in mind the overall goals of the hospital and the investment frame for the coming year.

All purchases above €2,000 and with an economic lifespan of more than 3 years are treated as investments and require a written commission to the PD. Figure 1 shows the schematic principle of the procurement process that is dealing with the purchasing of goods and services. The commission given to the PD from the division shows that top management has approved the investment and that there are funds allocated to make the investment. In cases when equipment which is necessary for the work at a department has broken down and can not be repaired there are always funds allocated to cover this type of “emergency” re-investments, but even these purchases must be handled according to the hospital purchasing process shown in Figure 1.

When the PD has registered the commission, a project plan is designed for it and the PD contacts different persons who will be involved in the project. It is obvious that the project team will include a number of persons from the department that will use the equipment, but staff from other departments is also required. One of the other natural participants to the project is the Clinical Engineering Department (CED), and if necessary, also representatives for the hospital property owner who will take care of all necessary re-

construction of the facilities. Staff from the PD will conduct a market analysis to get an idea of which vendors are available on the market, what specific features the equipment on the market has and roughly how much the investment costs will be. They will also be responsible to compile the official tender documentation that is needed, including the invitation to tender, the specification of requirements and contractual terms. The invitation is sent to the national Tender Journal and to different companies that have been identified during the market analysis. Investments that are larger than €200,000 will be announced in the EU’s Official Journal.

The specification of requirements plays a very important role in the whole purchasing process. It is written by the end-users and the CED and it is very important that these two groups have a good dialogue and co-operation from the very beginning. This dialogue must result in a documentation including explanation how the equipment will be used from the medical point of view, what special features are required for the desired medical function and what specific information will be needed to evaluate different tenders. The requirements should be formulated in such a way that the tenders will not apply only to a specific type of equipment. In addition, the requirements should not be formulated in such a way that there is a risk that some devices that might be suitable for the desired

clinical function will not meet the obligatory specification of requirements.

The CED will describe the basic technical requirements avoiding unnecessary details. The necessary technical requirements depend on the facilities where the equipment will be used; with what other equipment the new equipment will be interacting and what specific standards and safety requirements the equipment should comply with. Also, the requirement on training to maintain the equipment after the warranty period expires as well as the requirements of availability of spare parts during the expected lifespan of the equipment, the maximum delivery time of spare parts and access to new versions and upgrades. Looking over the devices' lifespan, the maintenance costs are often of the same range as the purchase price, especially if there are computers involved. For this reason, maintenance should be purchased together with the equipment in one package. In this way even the maintenance is subject to competition and it is possible to evaluate the costs, extent and quality of the maintenance in the same way as the cost of the devices themselves. Together with the end-user, CED will describe what accessibility to the clinical function is desired and what environmental demands the hospital has on the equipment and on the consumables. All the described demands must be measurable. At this stage the CED will also check if there are reports of accidents or risks of accidents where equipment for the desired type of diagnostics/treatment has been involved. This type of statistics is available nationally in Sweden, but there are also international databases available, for example on www.ecri.org website.

The review and evaluation of the tenders begins when the tenders have been opened by at least two persons, which is a regulatory demand. The purchaser then checks whether the tending companies fulfil the formal demands made by the hospital. One should always request references to hospitals where similar devices have been installed. Also, the tending vendors are asked to present their organisation, owners and financial status. It is also wise to check with the authorities that the submitted tenders do not have any re-

marks, because it is not good to have a long-term business with a company that becomes insolvent. Already at this stage some of the tending companies might be disqualified because they do not meet the formal requirements, or their tender is incomplete. The end-users and CED check how the tender meets the medical, functional and technical requirements described in the specification of requirements. If something turns out to be unclear, the tenderer might be given a chance to clarify a detail in their tender. The tenders can be evaluated by different methods, however, the method used has to be announced in the invitation to tender. In a very simple case the lowest price is used, but for more complicated purchasing objects a number of factors are evaluated and these factors are usually given different weights. The factors are specified in the specification of requirements so that the tending companies can describe them in their tender. These factors are for example the ergonomic properties of the equipment, quality properties, functionality and the environmental properties. The price or the running costs of the device as a value factor related to the performance of the equipment is also important for the evaluation, and in this context the Life Cycle Cost of the equipment will be calculated. The calculation includes the total cost of the investment; equipment price, installation, reconstruction of buildings, electrical supply, air conditioning, training of personnel, consumables, software licences, maintenance, spare parts and disposal of the device. The evaluation process thereafter results in the decision to select the vendor. It is important to document the whole evaluation process accurately based on the requirements and criteria stated in the tender documents. All the tending companies are informed about which company was selected and for what reasons and the competing tenders have the right to appeal against the decision within 10 days.

The contract between the hospital and the vendor should be written in an explicit way, using relevant parts of the text in the tender and vendor's replies to facilitate the transparency required by the Act of Public Procurement. The vendor's information concerning

their performance, training of personnel etc. shall be included as an attachment. The contract should describe all the practical details for the delivery of the equipment such as installation, supply of accessories, consumables, spare parts, user's manual and technical documentation, including service manuals. All open issues and final terms such as the length of the warranty time and how it will be calculated, service during and after the warranty time, must be written down.

All medical devices that do not need stationary installation are delivered to the CED for inspection and acceptance testing. CED will see to that the installation and the controls of large equipment such as MR are done by a third party consultant. When all the tests and inspections are done and the eventual lacks and short-comings in the delivery have been adjusted, the vendor is informed that the delivery has been accepted and that the warranty time has started.

During the warranty time the performance of the equipment is monitored and the commitments of the vendor are followed up. For example the down-time of the equipment should not exceed the one agreed in the contract, and if this happens the vendor is required to pay a penalty or the warranty time is prolonged. The PD will follow up the contractual issues and CED will follow the performance of the equipment. Both the PD and CED will keep contact with the vendor and inform them of the performance of the equipment and also discuss eventual improvements that, of course, can lead to price adjustments.

4. Discussion

There have been problems with a number of past investments in Stockholm. These problems have involved costs that have been several times higher than expected at the beginning, or equipment that has been impossible to use due to insufficient functionality. Rising costs of the medical equipment and other investments together with problems of purchasing have caused the management to take action and get control over the whole process. The well defined procurement process that the hospitals in the County Coun-

cil have to utilize has reduced the number of investments that have failed. However, there is a lack of discipline when it comes to following the rules and sometimes even quite expensive medical equipment has been purchased without the PD's or CED's knowledge. In these cases there has been some type of agreement between an individual doctor and a vendor of a special equipment that has been introduced as test equipment from the beginning, but that has become "permanent" and "essential" for the work at the department.

There has also been rather extensive criticism against the purchasing process since many departments perceives that the time to get access to the new equipment has increased. The PD has analysed the process and introduced improvements during 2009 which are supposed to speed up the handling of the individual purchasing objects. They have also, together with CED started an information campaign to increase the understanding of the process. Since the projects are getting more and more complex both technically, financially and legally, the competence of the staff must be constantly improved. New criteria, e.g. environmental, social justice and equality also increases the demands that the persons dealing with the procurement process are facing.

The hospital has introduced an e-purchase system to facilitate the purchase of consumables and some accessories. In every department there are number of individuals who have access to the e-purchasing system and can order supplies. In the long run it is economic to buy these "volume" articles through the e-purchasing system, since the products are purchased centrally in the county Council, which means that they are affordable compared to buying them directly from the vendor. Unfortunately the County Council organization that handles the supplies has quite high duties and charges, so that in some cases it is cheaper for an individual department to buy small quantities of consumables directly from the vendor.

The County Council also has plans to implement the whole process in a computer application. The plan is to use the internal web so that all investments, i.e. purchase for an

amount larger than €2000, would be possible to handle on the computer. It would make it easier to keep track of the individual objects and for the end-user to follow the delivery process. These types of software applications are already used in some other County Councils in Sweden, but they still have some problems which have to be overcome before the system will work satisfactory.

The Act on Public Procurement is very strict and failure to comply with it can cost a great deal. Requirements that are described in the purchasing documentation limit the number of devices that can be offered, but if several of the requirements are formulated as questions instead, the possibility of limitation can be reduced. It is therefore wise to address a few, but essential requirements and complete the list with many questions. The questions may deal with the equipment construction, operating principle, installation conditions, technical and clinical performance, the possibility to use alternative consumables, etc. Usually it is easy to use an electronic form that is attached to the tender. Then all tending vendors have to respond to the questions in the same way, which will facilitate the tender evaluation since the responses can be compiled and sorted according to how well the answers corresponds to the stated requirements. When the selection of the vendor is made this filled-in formula can be used as a part of the order to control that all performance agreed will be included.

It is important to keep in mind not to state requirements of such properties that are mandatory for the medical equipment on the regulatory bases, which might be confusing. When describing the selection criteria in the tender documentation, it is important to be explicit and consider which selection criteria are the most important. The specified criteria must also be applied when tenders are evaluated. Therefore, it is good to specify as few selection criteria as possible and then rank them. It is also advisable not to use so many must-requirements, i.e. requirements that the vendor must in all circumstances fulfil, because otherwise their tender is disqualified. Express instead the use of the equipment and request tenders for devices that are appropriate for the specified clinical function.

This will enable all appropriate devices, even those one does not know of, to be tendered. It provides a greater choice and enhances the competition.

Technical development of medical devices and solutions is fast and it is not unusual that devices that are still in the late development stage are offered. The advice is to avoid accepting this kind of offers. Problems that can be faced are for example that the delivery time is difficult to keep and new untested devices very often have functional weaknesses, which cause problems and additional costs for the clinical use. There might be additional costs involved even when purchasing systems in which several devices are interacting, especially if several vendors are involved. Sometimes the customer meets vendors who consider that they have fulfilled their part of the delivery, but still the clinical function of the system requested for has not been reached. If several vendors are going to interact in order to achieve the desired function, it is wise to appoint one of them as responsible for the complete system. This usually means that the vendor who is appointed responsible for the complete function engages others as subcontractors.

In Stockholm, hospitals have quite similar needs regarding medical equipment. Karolinska has of course some special features and therefore equipment that the other hospitals not have, but there are a large number of same types of equipment. To facilitate the management of this equipment, a co-operation project between different hospitals started in 2007. There is a project group with representatives from every hospital in Stockholm who inform each other of the forthcoming investments. The goal of this project is to co-ordinate purchasing of medical equipment whenever possible because, as already stated earlier large volumes give better prices and terms. So far there have been only few purchase projects that have been commonly carried out together with other hospitals, but the experiences are encouraging; economics of scale have made it possible to reduce price and also to negotiate options for other hospitals.

5. Conclusions

The improvement of the procurement process on different levels of the regional healthcare system has proven to be successful. Different parts of the procurement process have become clearer to the persons who are involved and it has resulted in reductions of the time needed for individual investments. In conclusion the improvements

of the process has resulted in a reduction of the investment costs not only in terms of the time used for each individual object, but also in terms of some advantages when large purchase volumes are possible.

Reference

1. OECD Health Data 2009: Statistics and Indicators for 30 countries, 2009