THE LOWER LIMB PROSTHETIC DEVICES QUALITY MANAGEMENT

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Abstract - Lower Limb Prosthesis is an artificial external device that replaces all or a part of the lower extremity. Prosthesis is used to provide an individual who has an amputated limb with the opportunity to perform functional tasks, particularly ambulation (walking), which may not be possible without the limb. The design of the prosthesis is dependent on the functional level of the patient and is geared toward comfort and minimizing limitations. There are several levels of lower limb amputation, including partial foot, ankle disarticulation, transtibial (below the knee), knee disarticulation, transfemoral (above the knee), and hip disarticulation. Therefore, the component parts of a lower limb prosthesis include a prosthetic foot, knee, and ankle, a pylon (to provide vertical support), and a socket (to hold the residual limb).

Lower limb prosthetic care services have two stages: prosthesis fabrication and rehabilitation of the prosthetic gait. The prosthetic health care team is an interdisciplinary team which includes: surgeon, rehabilitation MD, neurologist, diabetologist, nutritionist, nurse, physical therapist, prosthetics technician, prosthetics engineer, occupational therapist, social worker, prosthetics health care quality specialist.


The lower limb prosthetics, in terms of European and national regulations, are custom made medical devices. For the purposes GD 54/2009 (European Directive 93/42), we know that the custom-made medical devices manufacturer must comply with the indication from prescription and issue a declaration of conformity covering specific product characteristics described on the prescription.

The most durable and widely cited definition of healthcare quality was formulated by the Institute of Medicine (IOM) in 1990. According to the IOM, quality consists in the “degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” World Health Organization defines the healthcare quality as „The intrinsic achieve the goals of the health system to improve health and overall responsiveness to the expectations of the population”. The Prosthetics Care Quality must to be focused on the patients needs and expectations and the prosthetics devices providers must respect the quality assurance procedures in terms of patient safety to avoid all the possible medical devices adverse effects and/or the possible medical devices sentinel events.

The prosthetics care quality management’s main core must be the identification of the root cause of the quality problem which could appear and to find out the most easier way for a permanent quality improvement. It is mandatory that all prosthetics health care outcome to be patient centered in terms of amputee’s satisfaction (patient satisfaction).

Keywords: Prosthetics care services quality management, prosthetics gait rehabilitation, custom made medical device, amputee’s safety, amputee’s satisfaction.

1. Introduction

Lower limb prosthetic care services has two stages: prosthesis fabrication and rehabilitation of the prosthetic gait. In fact, when we speak about prosthetic rehabilitation process we must to take into consideration many factors: technical factors speaking about the “human spare parts” (artificial joints, prosthetic feet and others), technical and medical abilities of the practitioners, medical status of the amputee, capacity of support of the amputee’s family, technology of custom prosthesis fabrication, research and development in the prosthetic field, financial status of the patient, legal environment (laws and regulations), environment,
governmental healthcare policies. In terms of quality management it is not so easy to combine the things so that in the end, when we analyze the results of Patient Satisfaction Questionnaires we could be proud of our work.

In healthcare system, losses appear continuously, which induce huge costs for all society. These losses are generated by many causes: medical technologies or healthcare services less effective or ineffective, variations in performance, practice and outcomes between different healthcare services providers, unequal access to healthcare, patient dissatisfaction regarding to the received services, increasing of waiting time for receiving health services. Under these conditions, quality of care is a priority for health care providers, managers, patients, third party payer and government bodies alike. The providers of the healthcare services are eager for the recognition of their competencies. Patients are interested in receiving the necessary healthcare services as soon as possible from the chosen provider, with full respect for their rights. Payers are interested to introduce standards, criteria and indicators of quality in healthcare services facilities to keep costs under control. Above all, the government must regulate the healthcare system through legislation to facilitate implementation of quality management for all the healthcare services providers.

The concept of quality, in terms of prosthetics care providing, has three basic dimensions:
1. Professional quality – the prosthesis meets all the conditions set in the best practice standards;
2. Quality in terms of the amputee’s satisfaction – the amputee’s expectations from the new prosthetics device;
3. Total Quality Management – the prosthetics team must obtain the most efficient results using the resources inside the limits set by the authorities / prosthesis wearer

2. Need for quality of prosthetics rehabilitation healthcare services

Why do we need quality for prosthetics rehabilitation healthcare services? The answer could be simple: “We have amputees, not illnesses!” The prosthetics rehabilitation process is a dynamic process. In terms of exoprosthesis we know that they are custom made medical devices. One of the process’ inputs is the lower limb amputee. We must continuously adapt the process for different reasons: medical status (functional and cognitive), level of amputation, age of the patient, body mass index (BMI), stage of prosthetics rehabilitation. The initial assessment of the patient is a very important tool for customizing the rehabilitation process. The main core of the initial assessment is the identification of the amputee’s needs and expectations. It is a priority to have a patient centred approach to obtain as output patient satisfaction and patient safety.

Therefore, we intend in that paper to show how we can improve the quality of the prosthetics rehabilitation healthcare services using the tools and techniques of quality, starting with the identification of the quality problems and proving that it is a real quality problem.

3. Quality backgrounds

It is mandatory that when we start a project for quality improvement to understand the quality concept. Without this understanding, it would be impossible to design the interventions and measures used to improve the results.

The dimensions of the healthcare quality are:
Effective, delivering health care that is adherent to an evidence base and results in improved health outcomes for individuals and communities, based on need;
Efficient, delivering health care in a manner which maximizes resource use and avoids waste;
Accessible, delivering health care that is timely, geographically reasonable, and provided in a setting where skills and resources are appropriate to medical need;
Acceptable/patient-centred, delivering health care which takes into account the preferences and aspirations of individual service users and the cultures of their communities;
Equitable, delivering health care which does not vary in quality because of personal characteristics such as gender, race, ethnicity, geographical location, or socioeconomic status;
Safe, delivering health care which minimizes risks and harm to service users.

The International Classification of Functioning Disability and Health (ICF) defines disability as a result of an interaction between a person (with a health condition) and that person’s contextual factors (environmental factors and personal factors). The persons with a lower limb amputation are disabled people. The quality of the prosthetics rehabilitation healthcare from this point of view must be effective (the process outcome is based on the needs of the amputees and communities which are responsible for disabled people reintegration); efficient (in terms of cost – efficiency and time to reintegration); accessible and amputee-centered; equitable (in terms of respecting the rights of disabled people); safe (in terms of the amputee’s safety).

Donabedian describes the quality of health care as “That care which is expected to maximize the size of the welfare of patients, taking into account the balance expected gains and losses that occur in all stages of health care”. The Donabedian Model is a conceptual model that provides a framework for examining health services and evaluating quality of care. According to the model, information about quality of care can be drawn from three categories: “structure,” “process,” and “outcomes.” Structure describes the context in which care is delivered, including hospital buildings, staff, financing, and equipment. Process denotes the transactions between patients and providers throughout the delivery of healthcare. Finally, outcomes refer to the
effects of healthcare on the health status of patients and populations. The quality approaches are: healthcare services quality, quality control, quality assurance, and quality improvement, total quality management, performance excellence – key performance indicators (KPIs).

The techniques for quality measuring (patient satisfaction) are: patient questionnaire, patient interview, fake patient method, focus group, literature and research.

The quality tools are: basic quality tools (brainstorming, histogram chart, Pareto chart, QQUQCQQ quis, quid, ubi, quibus auxilis, quomodo, quando or who, what, where, when, how, why, fishbone/ Ishikawa cause-effect diagram, process flows, data verification sheets, other graphics) - are tools for solving problems detected in the process of quality improvement and quality management tools or so called “new tools of quality” (affinity diagram, the tree diagram, relationship diagram, matrix diagram, decision diagram, sagittal diagram, factorial data analysis) take into account the ideas of several members of a group and build a consensus in order to clarify a problem, determining the causes and actions.

4. Applications of quality improvement

First step was the identification of quality problems. The analyze of patient satisfaction questionnaires and the patient interview forms showed that 25% of the interviewed / surveyed patients were dissatisfied by the result of the prosthetics rehabilitation healthcare. There were many different reasons such as: insecurity gait, unbalance, prosthesis mass (to heavy) for the patients with primary prosthesis and waiting time between hospitalizations for old prosthesis wearers. Prosthetics rehabilitation healthcare process is a continuous process. The old prosthesis wearers need to come often in this kind of facilities because the gait disorders and compensatory movements induce joint pains and muscle contractures.

The indicator is a quantitative measure used to monitor and assess the quality of the organization, practice and support functions which may affect the results. The indicators used in healthcare quality management are listed in Table 1.

The quality improvement in the prosthetics rehabilitation healthcare facilities shall be made by an interdisciplinary team. Each member will need to have some clear goals to accomplish. They will need to understand the basic concepts in improving the quality, environment and identify key steps for a successful project to improve quality.

Table 1. Healthcare quality management indicators

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The analysis based on process results: for optimum process - optimal outcome. For an optimal process, the problem that can be prevented and these problems that can be corrected should be identified. Optimal outcome consists in correcting the problem that could be corrected and preventing the problem that could be prevented. The process’ complex problems require multidisciplinary solutions.

We could be in the situation where we can see “blackout” of the system, process errors and variations of performance and these things give us a competitive advantage. Improving the quality features: better patient care at lower costs and healthcare services paid by performance.

We should try to define quality based on the needs and expectations of our patients and try to provide them everything that they and their families want. A quality improvement method is not yelling to people to work harder, faster, or safer. There must be created protocols, and then monitoring their use and effect. We apply traditional methods of Quality Assurance or research methods.

Improving the quality of a system means changing the system. Changing the system should be made simple, and operate at micro level, otherwise we will hit the resistance to the change. You must first provide a favourable atmosphere for the change.

Step two consists in forming a multidisciplinary team and defining the change approach. A criteria for participation is experience and expertise. The team consists in a leader, expert and process owners. One of the tools used in the engineering of the change is the cause and effect diagram.

Figure 1: Classification of functional components: ankle – foot unit

The lower limb prosthetics rehabilitation management consist in two stages: pre-prosthetics management and prosthetics training. For the patient with primary prosthetics device an usual first feed-back is “too heavy”. But after a few days of prosthetic gait training, the amputee has enough time to accommodate with the prosthesis. When we obtain such a high percentage of dissatisfied patients it means that we have a real quality problem.

For confirming that we analyze all the initial assessment forms. Statistically speaking, we find out that almost all dissatisfied patients were equipped with a endoskeletal primary transtibial prosthesis.
The next verification was if the fabrication of transtibial prostheses technical procedure and also the selection prosthetics components technical procedure is well implemented and used. We analyzed also the standards of functional components in principal just for ankle-foot unit because we take into consideration just patients with a unilateral transtibial amputation.

Speaking about the instability and unbalance as dissatisfying reasons, all members of the quality improvement team agreed that wrong prosthetic feet were selected. In fact, the root-cause of the complaints was related to the custom made medical device - the prosthetics device.

After the identification of the complaints’ cause it was performed an audit of supply inventory management. As results and recommendations: strengthening Management of Prosthetic Supply Inventories will reduce costs and minimize risks of shortages.

The organization needs to strengthen organizational management of prosthetic supply inventories to avoid spending funds on excess supplies and disruptions to patient care due to supply shortages.

The organization also needs to improve the completeness of its inventory information and standardize annual physical inventory requirements.

The organizational management did not maintain optimal inventory levels because of the following reasons:
- Lack of integration between the prosthetic inventory system and other organizational systems
- Inefficiencies from using two inventory systems
- Inadequate staff training on inventory management
principles and techniques
- Insufficient external audit oversight of the organizational inventory management practices
- Inadequacies in Organisational Inventory Management Handbook

After the finish of the quality improvement process to achieve the main goal: decrease by 25% of complaints related to the prosthetic device. One way of improving the quality was quality assurance manual revision, in particular the supply and internal communications operational procedures.

5. Conclusions

While most companies focus efforts on improving supply chain efficiency by looking at the supply chain process itself, a few realize that other departments can have an impact on efficiency and speed. One of these departments is Quality, which is tasked with inspecting incoming raw materials, in-process work and final product before it is delivered. If there is a way to help the Quality department get its job done faster, then, by definition, the operations process can move along faster, thus reducing time in the supply chain.

On the other hand, the Quality Department from a Prosthetics Rehabilitation Healthcare Facility has a heavy duty because of the variety of factors which contributes to the amputee’s satisfaction.

6. References