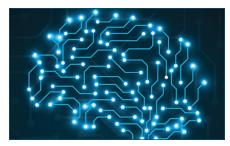
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ABSTRACT

The robot-assisted rehabilitation is a type of technology that has shown great advances in recent years, demonstrating its effectiveness in different neurological disorders; however, the main argument against the introduction of robot technology in rehabilitation is economic considerations. Herein, we discussed the main concerns related to the widespread use of innovation technology and the need for a costeffectiveness analysis to enter robotics into the framework of the healthcare systems involved in neurorehabilitation.

KEYWORDS: Innovation technology, neurorehabilitation, functional recovery, healthcare system, reimbursement

Who Will Pay for Robotic Rehabilitation? The Growing Need for a Cost-effectiveness Analysis

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The robot-assisted rehabilitation is the type of technology that has shown the greatest advances in the last years. A robot is defined as a reprogrammable, multifunctional manipulator designed to move material, parts, or specialized devices through variable programmed motions to accomplish a task. In particular, the robotic neurorehabilitation devices are typically based on the so-called phenomenon of motor learning, resulting from intensive, repetitive, and task-oriented motor activities that require a patient's effort and attention.¹

The robot-assisted rehabilitation extensively demonstrated to be effective in the functional recovery (including improvement in gait and upper limb function) for patients with traumatic brain injury (TBI), spinal cord injuries (SCI), stroke, as well as with cerebral palsy, Parkinson's disease, and multiple sclerosis.^{1,2} Patients achieve better results when robotics is coupled with virtual reality.³ Nonetheless, the widespread use of innovation technology in the rehabilitation field is limited by several issues. Indeed, there are numerous economic barriers to the adoption of robot technology in rehabilitation, including adequate evaluation and cost-effectiveness techniques, reimbursement models, and other incentive mechanisms.⁴

Robot-technology for rehabilitation requires high levels of investments, and its maintenance and routine operation are relatively costly, depending on the type of rehabilitation.⁵

However, this is not because doctors and therapists do not consider the use of robotic systems necessary and patients do not benefit from it. The decisive reason for the lack of dissemination is solely the question of reimbursement. In neurological rehabilitation, the question of which treatments a patient receives and for how long is not determined by his or her needs and medical necessity, but by the level of the cost rate paid by the respective insurance company. Thus, by definition, care from which patients benefit in the best possible way is not feasible.⁶

The main argument against the introduction of robot technology in rehabilitation is economic considerations. It is often said that treatment with robotic systems is expensive. Nevertheless, what do we compare, and what does expensive actually mean? If we compare treatment with the use of robotic systems to the cases that we do not treat, the treatment with robotics is certainly more expensive.⁷ If we compare treatments using robotic systems to conventional treatments, the situation is guite different. Initial studies show that patients who are treated with robotic support when necessary recover faster and better than those who are treated conventionally.^{1,2} In the short term, the relatively high investment and maintenance costs must certainly be taken into account.

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To date, detailed and rigorous studies on the economic sustainability of robotic technologies for rehabilitation are very sporadic. Concerning upper limb, the VA ROBOTICS study demonstrated that, although providing additional care using new technology can be expensive, the total costs (including therapy and healthcare costs) were not greater for the robot group than the usual care group.⁸ In their recent meta-analysis, Carpino et al⁷ demonstrated that robot-assisted gait therapy has proven to be more effective than conventional therapy in the treatment of patients who were stroke-affected, as overall OR results had shown that the robotic therapy enabled a larger number of patients to recover independence in walking. In the economic sense, robotic therapy based on the use of wearable robots has proven to be expensive, and the gap between the cost of robotic and conventional therapies is considerable. However, costs decrease as the hours of possible use of the robot increase. Moreover, robotic therapy based on the use of operational machines is the most economically sustainable method because of the low purchasing cost.⁷

In the Italian rehab field, inpatient reimbursement is related to the code to which the patients are assigned based on the neurological damage. Patients with SCI are classified as Code 28 and reimbursed 470€ per day; the same reimbursement is given for inpatients with severe acquired brain injury and rare disease (Code 75). On the other hand, patients who had a stroke and with multiple sclerosis, as well as those with Parkinson disease, are assigned to code 56 and reimbursed 270€ per day (but they can attend the inpatient regimen up to 60 days, whereas 28 and 75 codes may attend the hospital as needed).⁹

There is a different approach in many European and American countries. Generally, the German health system pays what is necessary as prescribed by a doctor.¹⁰ In practice, however, the public health insurance funds do not provide sufficient means to run sufficient rehabilitation clinics or centers, especially for outpatients.¹¹ Moreover, they object the reimbursement of robotic-assisted therapy. They argue it is a new therapy method, and that the evidence is not proven yet. Patients in Germany seeking robotic-assisted therapies will have to pursue financial support from their insurer on a case-by-case basis, which can be lengthy and costly.¹²

Insurance companies regularly refuse to cover the costs of treatment with robotic systems on the following grounds:

- The therapy applied for is a new examination and treatment method that has not yet been adequately evaluated.
- The health insurance has concluded that conventional treatment methods are sufficient.
- Therefore, the health insurance company is unfortunately not allowed to provide the requested services. It must observe the principle of economic efficiency.

However, the question of the use of robotics must not be considered primarily from an economic standpoint. It is only through the use of robot systems that it is possible today to treat people with severe motor dysfunctions at all.¹ Patients who are unable to walk cannot undergo effective gait training without robot support. Walking can only be established through intensive and very repetitive training, which is not possible with conventional methods, not even through the use of several therapists at the same time.¹² If one considers the guestion of assuming the treatment costs with robot systems, the question arises whether there is a claim to effective gait training or whether it is sufficient for a society to provide these patients with a wheelchair that also offers mobility.¹³ When do insurance companies have to cover the costs of treatment with robotic devices? Is it up to the insured to decide, or are they entitled to cover? The International Covenant on Economic, Social and Cultural Rights (ICESCR) might provide information. Article 12 of the ICESCR states: "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."

In its General Comment No. 14,¹⁵ the competent Committee on Economic, Social and Cultural Rights (CESCR) stresses that Article 12 of the ICESCR states that, in addition to the right to physical integrity and self-determination, there is also a legal right to a health system that enables all people equally to achieve the highest attainable standard of health (for them personally). For the committee, public health services and institutions must meet four criteria: they must be available, accessible, acceptable and of sufficient guality.¹⁶ Availability means that sufficient functioning medical facilities and services must be available in the member state, whereby the requirements for their type depend on the development status of the respective country. The criterion of quality aims to ensure that healthcare facilities, drugs, equipment and services meet medical, scientific and hygienic standards and provide good quality treatment by trained and competent personnel. In implementing its obligations, the state retains a margin of judgment; in particular, when developing a national strategy, it reserves the right to assess which measures are best suited to the conditions in the country.¹⁶ What does this mean? Does this mean to grant patients an endless treatment? What determines the discretion, what is appropriate and must be maintained or paid? Different national health systems have given different answers. Some limit the time of treatment, some the number of treatments.

The discretion is determined by various factors. One of them is the previous action. In the acute phase, the frontier that can be achieved for a patient has been moved forward further and further.¹⁷ Today, we keep severe brain damage alive no matter of costs.¹⁸ lf a society is willing to pay for this, and thus creating expectations on the patient side, the society cannot stop adequate support in the rehabilitation phase but must provide the same level of aftercare and rehabilitation. Here, it cannot retreat to a much lower standard without error of judgment. Otherwise, it violates the principals of the ICESCR.¹⁵ This does not create a directly enforceable right of an individual patient to claim reimbursement but requires the national health systems to provide sufficient rehabilitation services and grant patients access to state of the art therapies also with robotics.

However, costs of new technology might be considered the main reason why hospitals, especially those operating in the public systems, might be reluctant in adopting them in rehabilitation. The measurement of value is also a barrier to their adoption. There is a long way to get agreement among the various players in the healthcare system concerning

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the nature and measures of the value they desire and actually obtain from the adoption of new technological devices.⁴ For example, lower expenses might occur in the purchase of the new device, but the costs might sharply rise when one computes the operational and replacement costs. Moreover, education of a skilled therapist and the often-high cost of a device's maintenance might worse this concern.

In conclusion, robot-technological solutions for rehabilitation often remain at a feasibility study stage where effectiveness is probably more important than the economic sustainability. In fact, effectiveness is less difficult to prove than the economic efficiency and sustainability of the designed solution in the short, medium, and long term. Nonetheless, from a healthcare system perspective, further studies with larger samples are required to fully understand the cost-effectiveness ratio of robotics to provide patients with the best treatment options, also taking into account its sustainability.

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