ROBOT-ASSISTED REHABILITATION AND ELECTROMECHANICAL DEVICES FOR PEOPLE WITH NEUROLOGICAL DISABILITY "CICERONE"

Final document by the Jury

This document is an abridged version of the final document produced by the Jury, produced for the purpose of making the main findings of the Conference easier to access.
It contains summaries of the evidence and a summary of the Jury's concluding remarks.
It does not contain details of the data collection and processing process carried out by the working groups to arrive at the summary of the evidence, nor the related bibliography.
It does not contain details of the rationale by which the Jury arrived at the concluding indications
For a complete understanding of the methodologies and results of the Conference, please refer to the full version of the final document.

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PRESENTATION

REASONS FOR THE CONSENSUS CONFERENCE

The use of robotic technologies in rehabilitation has experienced a steady increase in recent years, and it is expected to expand further in the near future.
The availability of devices of relatively simple use, usable in the clinical setting, has led to their spread. In Italy, these technologies were included in the Essential Levels of Assistance of the National Health Service in 2017.
There are inhomogeneities and discrepancies in the criteria and practical methods of clinical use of these technologies. To promote the development of an overall and shared framework of reference, with reference to disabling diseases of neurological origin, the Italian Society of Physical and Rehabilitation Medicine (SIMFER) and the Italian Society of Neuro Rehabilitation (SIRN), with the support of the Istituto Superiore di Sanità (ISS) have promoted the organization of a National Consensus Conference, considered the most appropriate way to address this problem.

PURPOSE OF THE CONFERENCE

The aim of the conference was to develop recommendations on:

- definitions and criteria for the classification of devices;
- clinical use of the devices in the most frequent disabling conditions of neurological origin;
- theoretical reference models for the development and clinical use of devices;
- appropriate organizational contexts for the use of the devices;
- regulatory aspects, social, ethical and legal implications of the use of devices.

METHODOLOGY

The methodology for the development of the CC was based on the criteria proposed by the Manual published by the Istituto Superiore di Sanità in 2013 (National System Guidelines-Guidelines – How to organize a consensus conference – update November 2013- https://www.psy.it/wp-content/uploads/2018/02/Manuale-Metodologico-Consensus.pdf).
A Promoting Committee (CP) and a Technical Scientific Committee (CTS) were set up, composed of representatives of professions, institutions and other organizations involved in the problem, which defined the questions to be submitted to the Jury.
9 working groups (WG) have also been set up, with the task of collecting documentary material to be submitted to the Jury.
A Jury with characteristics of competence, multidisciplinarity and multi-professionalism examined the material and elaborated the indications in response to the questions (Table 1).
A Writing Committee oversaw the drafting of the final document.
The work of the Conference took place between January 2019 (constitution of the Organizing Committee) and December 2021 (approval of the final Consensus document).

Table 1 - QUESTIONS FOR THE JURY

1) Device classifications. Which devices fall into these categories? What are the existing classifier systems? Which classifications to recommend?

2) In the light of existing knowledge, what recommendations can be made regarding the use of these devices in everyday clinical use? Which endpoints should we use?

3) What are the most relevant theoretical reference models for the development of these devices? What are the most promising future prospects? What recommendations to provide for development and research?

4) Which organizational contexts appear most appropriate for the use of these devices in the clinical rehabilitation field for people with disabilities of neurological origin?

5) Which training paths/skills are recommended for operators?

6) What recommendations can be given regarding the regulatory aspects (e.g. risk management, off-label use, etc.), ethical, legal and social aspects of the use of these devices and their social acceptability in a broad sense?

At the end of the work that took place between 2020 and 2022, the Jury of the CICERONE Consensus Conference formulated the following observations and indications.

A1. Definition of robot-assisted rehabilitation and device classifications

A1.1 What is robot-assisted rehabilitation?

Robot-assisted rehabilitation is to be considered part of the rehabilitation intervention that aims to integrate standard rehabilitation treatments through the interaction between rehabilitation professional, patient and robot. The latter are equipped with adaptive control systems that allow to individualize the rehabilitation intervention according to the needs and specific residual abilities of each patient in order to promote sensorymotor, cognitive and behavioral recovery. Robot-assisted rehabilitation treatments allow **to increase the intensity and/or frequency of therapeutic interactions, to enrich the sensory experience and/or to facilitate the execution of environmental actions and interactions.**

A1.2 What classification criteria can be deduced from the existing literature?

To consider a technology "robotics" it must undoubtedly be equipped with all four of the following subsystems:
- mechanical support;
-implementation;
-sensors;
-control.

A1.3 What other classification systems should be considered?

In the formulation of Public Health documents, the Jury considers it essential not to consider studies concerning robotic devices without CE marking or in the prototype phase because they could not be immediately applicable in health contexts. Therefore, although the importance of studies at the prototype stage is recognized for the development of science and technology, studies concerning these cases will not be taken into account in this document.

A1.4 Relating the existing literature, what types of devices have been used in clinical use for the rehabilitation of the upper limb, gait and balance in adulthood and in children?

In the reporting of experimental and observational studies concerning the use of robotic devices in rehabilitation, in order to be able to analyze the clinical results also in the light of the specific characteristics of the device, **it is necessary that the characteristics of the system used are explained as in the following table.**

CE marking	□ present □ absent
Stage of development	□ on the market □ prototypical
Type (mechanical system characteristics)	□ end effector □ exoskeletal
Displacement in space	□ overground □ non-overground
Macrofunction/body district	□ lower limb/ambulation/balance □ upper limb/ reaching/manipulation
Upper limb body districts	□ 0= all upper limb □ 1= shoulder and elbow □ 2= shoulder, elbow and wrist □ 3= elbow, wrist and hand □ 4= elbow and wrist □ 5= elbow □ 6= wrist □ 7= wrist and hand □ 8= hand
Purpose of use	□ interactive/ reductive □ assistive/compensative
Modes of assistance (Basteris, 2014)	□ passive mode: the robot performs movement without contribution from the subject; □ active: the robot exerts no force on the patient's limb; □ assisted: the robot assists movement through weight relief or by exerting forces to help the subject; □ active-assisted: the robot provides assistance only when the subject is unable to actively perform it; □ passive-mirrored: bimanual devices whereby the healthy limb controls the passive movement of the affected limb; □ corrective: the robot stops the movement in case of error by the patient; □ path guidance: the robot guides the subject when it deviates from the predefined trajectory; □ resistive: the robot opposes movement by the subject.
Environment	□ real □ virtual
Presence of feedback to the user	□ none (0) □ visual (1) □ haptic (2) □ auditory (3)
Degrees of freedom of movement	□ 1 □ 2 □ 3
Dimensions of movement	□ 2D □ 3D
Adjustable parameters	□ Force □ Kinematics □ ROM □ EMG □ pressure

A2. Theoretical fondamentals of the use of robotics in rehabilitation

A2.1 Are there theoretical reference models for the use of robotic equipment in the rehabilitation of people with disabilities of neurological origin?

The Jury considers it a priority to carry out studies aimed at identifying the possible role of the use of robotic devices in stimulating neuroplasticity.

PART ONE.
SUMMARY OF EVIDENCE FOR THE USE OF ROBOT-ASSISTED REHABILITATION IN PEOPLE WITH NEUROLOGICAL DISABILITIES

In consideration of the level of evidence collected so far by the working groups and the evaluations conducted on the available material, the Jury believes that it cannot formulate "Recommendations" but exclusively "Summary of evidence" which are therefore to be considered indicative.

SUMMARY OF EVIDENCE

B1. Recommendations in neurological disabilities in children

The rehabilitation approach with robotic devices constitutes a recent therapeutic opportunity for the treatment of motor disorders of children with neurological disabilities. The literature examined did not allow to identify guidelines and meta-analyses for the drafting of certain recommendations for children. Overall, however, some common positive aspects of the use of robotics in pediatric rehabilitation emerge from the analysis of the literature: first of all, **the child's playful approach to robotic training that motivates and stimulates him to improve his performance, and the substantial absence of side effects.**

As far as **the upper limb** is concerned, **the results generally appear promising**, even without the need to subject the patient to an excessive number of sessions. In particular, an improvement in the fluidity and speed of reaching movements is reported. **The potential feedback (sensorimotor, motor learning) guaranteed by robotic therapies can be personalized and increase the effects on the task and motor learning by the subject. Robotic gait rehabilitation** has been studied mainly with non-overground exoskeletal robots that allow the relief of body weight in children with outcomes of Cerebral Palsy. Robotic therapy with such devices appears promising, demonstrating **benefits in terms of distance, speed, endurance and balance**, but with insufficient evidence due to heterogeneity in treatment duration, number of weekly sessions and sometimes association with conventional rehabilitation.

With regard to rehabilitation for **the lower limb it is difficult to deduce universally applicable conclusions** for paediatric rehabilitation as the positive results are in most cases derived from an experimental setting. The outcomes report an overall improvement in biomechanical, clinical, spatio-temporal, kinetic, kinematic and electromyographic parameters in patients subjected to gait analysis.

B2. Recommendations in neurological disabilities in adulthood.

B2.1 Upper limb dysfunction and recovery of the ability to achieve and manipulate

From the evaluation of the vast literature collected and analysed, and from the documented discussions developed by the Working Group, the Jury can summarize the following conclusions:

- positive effects on the functionality of the upper limb are currently poorly observed and reported in the literature compared to other problems;
- However, robotic therapy for the upper limb **may have therapeutic value** with regard to recovery of bodily functions according to the ICF system, in particular **motor control and muscle strength;**
- positive effects are also conceivable on the overall autonomy of the patient (ICF activity domain) in activities of daily living, due to a probable secondary effect of the recovery of the impairment;

– Most of the evidence relates to end-effector devices that have been on the market for longer. In the future, it will be interesting to evaluate the presence of a greater functional impact of exoskeleton devices that allow treatment with complex movements thanks to their high number of degrees of freedom;
– The most frequent patient population undergoing this type of treatment is **patients with stroke outcomes, both in the subacute and chronic phases.**

B.2.1.1 Stroke

Robotic therapy appears to have **positive effects on motor control and muscle strength** of the paretic upper limb in stroke patients. There is insufficient evidence to conclude that robotic therapy can improve muscle tone, pain, function, paretic limb dexterity, and perceived functional utilization in patients with upper limb paralysis affected by Stroke.
Robotic therapy can be considered as a treatment option **to improve the overall autonomy** of the stroke patient while there is no indication that robot-assisted therapy for the upper limb will affect participation.
Compared to the time of stroke (< 3 months; > 3 months), there is no significant difference in the effectiveness of robotic treatment.
Patients with increased motor impairment could use robotic treatments **to increase exercise intensity during rehabilitation**. It is not possible to hypothesize a greater effectiveness of one type of robotic device compared to another, rather **their different use based on the characteristics of the patient, the rehabilitation phase (subacute and chronic) and the objective** for which assisted robot rehabilitation is carried out for upper limb. Although the intensity and repetitiveness of the gesture are recognized as "determinants" of rehabilitation useful for motor recovery, it is not possible to deduce from the literature at what dose and with what frequency the different populations of stroke patients respond optimally.

B.2.1.2 Spinal cord injury

The robotic device approach now represents a feasible and safe therapeutic opportunity in the treatment of the upper extremity in patients with spinal cord injury.
Patients with mild to moderate residual function appear to benefit more from treatments using robotic devices than traditional therapy. Robot-assisted treatment could be effective **in significantly improving kinematics and fluidity of movement**. The benefits in terms of strength, function and independence in ADL reported by robotic rehabilitation studies in this category of patients are heterogeneous and not definitive in particular due to the very limited number of studies performed and patients enrolled.). On the duration and frequency of treatment there are no indications of consent given the wide heterogeneity of rehabilitation protocols in the literature and the different robotic devices used. **The combination of two different robots with respective complementary actions**, one with the aim of improving the outcome of the proximal part of the upper limb (**shoulder elbow)** and the other **the hand,** is feasible and equally effective at a comparable dose of conventional treatment.

B.2.1.3 Multiple sclerosis

The literature evaluation **does not reveal additional benefits of robot-assisted therapy for the upper limb compared to those of conventional rehabilitation.** The robotic devices used in upper limb rehabilitation in Multiple Sclerosis patients **still represent a therapeutic opportunity, improving manual dexterity, coordination, functional capacity and efficiency in upper limb motor strategies**. The literature does not agree on the duration and frequency of treatment, due to different protocols used in the various studies and it is not currently possible to demonstrate that the number of weekly sessions or the duration of treatment brings more evident results. It can be highlighted that the improvements obtained after intensive treatment are not always maintained in follow-ups, except in activities of daily living.
The beneficial effects shown after intensive treatment **tend to wear off over 6 months,** so regular management is recommended for these patients.
Patients with greater impairment could use robotic treatments to increase exercise intensity during rehabilitation. The expected benefits following these treatments should affect not only the narrow motor skills, but in general the degree of autonomy and quality of life of these patients, so it is always recommended to use scales to evaluate these two domains when prescribing a robotic treatment program.

The expected benefits as a result of these treatments are expected to affect not only the narrow motor skills but in general the degree of autonomy and quality of life of these patients, so the use of outcome measures to assess these two domains is always recommended when prescribing a robotic treatment program.

B.2.1.4 Other conditions (Parkinson's disease, GCA)

Since there is still not enough evidence to consider the use of robotic assisted re-education of the upper limb effective in patients with Parkinson's disease or with severe acquired brain injury. However, it is conceivable to use robot-assisted rehabilitation of the upper limb **to increase rehabilitation practice and counteract damage from non-use and in addition to conventional therapy.**

B2.2 Dysfunction of the lower limb and recovery of gait

B.2.2.1 Ictus

In the audited studies, numerous robotic technologies are used that are very different from each other, both from the point of view of mechanical construction and with respect to their control systems, and sometimes of a prototype type. As a result, reviews with meta-analyses are difficult to interpret and require caution as they group clinical trial data according to outcomes: 1) carried out with very different technologies; 2) in which the details of the robotic devices are not reported; 3) concerning patients with distance from the acute event and different functional levels; 4) concerning patients undergoing heterogeneous training and protocols.

We can identify **robotic devices more "suitable" for specific pathology and level of disability,** but, in terms of dosage o training and protocols, there is a great variability that makes it difficult to identify standards. The use of robotic rehabilitation as an additional to conventional treatment seems prevalent.

In patients with severe disability, or **FAC <4 (Functional Ambulation Category) it is suggested to use in acute and subacute phases.** An important Cochrane systematic review reports a **Number Needed to Treat of 7,** that is: of seven subjects treated within three months, one will go from FAC <4 to FAC≥4, regardless of the type of robotic device used. More specifically, patients with FAC > 3 show improvements in Time-Up&Go Test while those with FAC < 3 improved in the 6MWT test. In patients with FAC ≥ 2, an increase in strength and balance is reported in the group of patients with stroke (mean time from the event 3 months) treated with robotics in *add on* compared to the group treated with traditional rehabilitation alone. Robotic assisted gait training seems to have different effects based on distance from the acute event, as well as on the level of functional impairment. **Non-ambulatory patients started early robot-assisted gait training, in addition to conventional rehabilitation, derive greater benefits the worse their functional deficit were.** The temporospatial parameters of gait (in particular the support time on the paretic limb) also improve mainly in sub-acute patients. From the reviews that separately analyse the data of subacute and chronic patients, it is clear that the gait speed increases significantly, at the end of the robotic assisted training, mainly in sub-acute patients but not in chronic patients. In general, these improvements are all the more evident the earlier robotic training is started.

The improvement of the six-minute test, linked to resistance during walking, is also observable in patients in chronic phase.

In choosing the most appropriate devices, the literature divides robotic technologies into **"robot in charge" (RIC)** (the device guides the patient's movement within a fully imposed kinematics and no variations with respect to the trajectory of the movement are allowed) and "**patient in charge" (PIC)** (kinematic tolerances are allowed that allow the patient to interact with the system itself, instead of being guided passively). **The RIC modalities seem more suitable for use with more severe patients, while the PIC modalities seem more suitable for use with patients with higher motor quotas.**

Finally, some recent works have shown that robotic walking training **for at least 2 weeks can improve cardiorespiratory performance,** especially in patients unable to walk. The observed effects, in particular with respect to energy consumption and the reduction of cardio-respiratory stress, probably depend on the setting of the devices: degree of relief, level of assistance of the robot and speed.

B.2.2.2 Spinal cord injury

1.- Non-overground exoskeleton with relieving on "treadmill"

These robotic systems, applied in addition to conventional therapy, are able, in patients with **incomplete lesion**, **to improve clinical tests such as WISCI II, 10 MWT, 6MWT, LEMS and locomotor FIM scores** compared to conventional treatment alone, although studies do not specify whether conventional treatment is given the same intensity and specificity of locomotor training.

2. Dynamic exoskeleton overground.

Improvements after overground robotic training have been observed. This tool is relatively safe in both people with incomplete and complete lesion. The use of the dynamic exoskeleton has proven **effective in increasing walking ability (speed, endurance, ability) both in people with incomplete and complete lesion.** In some studies beneficial effects on **spasticity and pain** are observed and good satisfaction in using this dynamic exoskeleton. The use of the robotic exoskeleton for walking determines an increase **in muscle mass** and an improvement in **bone trophism,** evaluated with a bone densitometry system.

Experience of improvement in **gut management** is reported after robotic exoskeleton gait training.

B.2.2.3 Multiple sclerosis

Although today it represents **a therapeutic opportunity** in the treatment of gait deficits in patients with Multiple Sclerosis, recent literature does **not highlight benefits in addition to those obtained from conventional treatment classically carried out over-ground or on treadmills**. This type of treatment is an advantage when used on patient populations with **greater degrees of disability and less gait ability**.I t is certainly recommended the possible **association** of a specific treatment for the gait **with cognitive stimuli and in virtual reality environments**, which from the studies taken into consideration is certainly associated with a further beneficial effect on cognitive functions.

The **benefits** associated with these treatments affect not only the narrow motor skills, but in general **the autonomy and quality of life** of patients with Multiple Sclerosis.

The beneficial effects highlighted after intensive treatment **tend to run out over 6 months,** so the possibility of repeating the intensive treatment over time should be evaluated.

B.2.2.4. Parkinson's disease

The most significant studies (primary studies and systematic reviews of good or very good quality) were considered. Of these, 60% highlight a superiority in terms of effectiveness of robot-assisted treatment vs control in terms of improvement of gait characteristics, balance and functional outcomes of patients; the rest highlight that this treatment is still effective although not significantly higher than control.

On the basis of the scientific literature analyzed, therefore, **there is no evidence to date of superiority of robotic assisted training compared to treadmill training and / or other conventional therapies.**

B.2.2.5 Traumatic brain injury.

The available literature inherent in efficacy studies has weaknesses with regard to statistics due to the small sample taken and consequently the reduced power of the studies with a real risk of incurring the second type error. **No conclusive evidence can be given on the use of robotic treatment in the outcomes of Traumatic Brain Injury.**

B2.3 Balance dysfunction

B.2.3.1 Ictus

Gait rehabilitation with robotic walking devices has **positive effects on balance in subacute and chronic stroke** subjects who use this type of treatment compared with those who do not. In the studies considered, the best outcome is for subjects performing robot-assisted treatment in combination with conventional physiotherapy. The positive treatment effects on robot-assisted balance are not affected by the presence or absence of other types of combined approaches (FES, tDCS, Treadmill, and virtual reality). **High-intensity exoskeleton training (70% Heart Rate)** can bring additional benefits to balance **in chronic stroke subjects, also exoskeleton training and progressively reducing adaptive forces can bring additional benefits to balance in subacute subjects.**

Exoskeletal device treatment has positive effects on subacute and chronic stroke patients regarding **fear of falling (ABC scales) and balance-related gait parameters (double stance times and stride length**) measured by

instrumental motion analysis systems. **Combining exoskeletal treatment with FES functional electrical stimulation** can improve step length parameters.

B.2.3.2 Spinal cord injury

Activation of trunk muscles seems to be induced more by an overground exoskeleton-type device than by a non-overground exoskeleton-type device with body weight support. This effect could result in better postural control while seated.

B.2.3.3 Multiple sclerosis

An exoskeleton device appears to improve balance **in the immediate post-term treatment** (disappearance of the effect in long-term follow-up) especially if the same device is used **in combination with conventional gait training or with 2D virtual reality .**

B.2.3.4 Parkinson Disease

Although it emerges from the literature that robotic training is not superior to conventional therapy of equal intensity, studies show **significant improvement in both the UPDRS III score (which also includes items concerning balance) and the Berg Balance Scale immediately after robotic training and at a 1-month follow-up.** Robotic treatment may have beneficial effects on the **frequency and severity of Freezing of Gait.**

Studies show the **non-superiority of robotic training both against conventional treadmill training performed at the same intensity and against conventional treatment for postural instability**

B.2.3.5 Acquired Brain Injury (ABI)

An end-effector robotic tilt table system device appears to improve static balance immediately after the end of treatment (not maintained at the follow-up). There is level 4 evidence regarding the effectiveness of a lower limb electromechanical end-effector system type device in improving static balance. All robotic devices that had a positive effect on balance outcomes were used **within a multidisciplinary rehabilitation program or in combination with conventional walking physiotherapy.**

B.2.3.6 Other pathologies

Studies show the usefulness of **robotic training combined with Multidisciplinary Intensive Rehabilitation Treatment in improving postural control and reducing the number of falls in patients with progressive supranuclear palsy.**

PART TWO.

REGULATORY, LEGAL, ORGANIZATIONAL, TRAINING, ETHICAL, AND SOCIAL ASPECTS IN ROBOT-ASSISTED REHABILITATION IN PEOPLE WITH DISABILITIES OF NEUROLOGICAL ORIGIN

C1.1 What organizational settings seem most appropriate for the use of these devices in clinical rehabilitation settings for people with disabilities of neurological origin?

In light of the current evidence, no recommendation could be made as to which organizational contexts are most appropriate for the use of robotics in people with neurological disabilities.

Current national legislation does not currently facilitate the integration of robotics into patients' rehabilitation pathways. Regional regulations are varied and uneven. However, **it is suggested that Health Technology Assessment (HTA) logic and methods** be used whenever a new robotic technology is being considered for inclusion in a setting.

C1.2 What recommendations can be made regarding the regulatory (e.g., risk management, off-label use etc.), ethical legal and social aspects of the use of these devices and their broader social acceptability?

C1.2.1 General framework

In the current context of rapid technological development, we are witnessing rapid and widespread changes in the interactions between humans and machines, equipped with increasing autonomous movement capabilities.

New prospects are opening up for the use of robotic and "artificial intelligence" (AI) systems in various areas of human activity, including medical care.
The main synthetic criterion we can employ is that of **the centrality of the human being (and the patient**), so that robotic (and AI) devices operate as supports and not as substitutes (for the role) of people. This general criterion has some implications:
1. That **it is the human subject who maintains control of processes**, avoiding indiscriminate substitution or delegation to technology.
2. The promotion of **the doctor-patient (or health professional-patient) relationship** so that it becomes more efficient, accurate, faster and less costly.
3. The underlying concept of **human dignity**, which is susceptible to different interpretations in different philosophical and legal cultures, is understood in a relational sense. It requires that we maintain self-awareness and awareness of the difference between interactions that take place with a machine and those that take place with another human being.

Since the novelty inherent in these technologies requires a substantial investigative component, which moreover involves multiple disciplines, we divide the exposition into a first part that deals with **research and experimentation (A.)** and a second part that deals with **the use (B.-E.) of the devices considered**.

C1.2.2 Research-experimentation
Indications for engineers, computer scientists, and health care professionals
- Introduce the importance of the **ethical principles of beneficence, non-maleficence, autonomy, accountability, transparency, and justice**, in their articulation with integrity, vulnerability, and human dignity, into professional codes of conduct and training courses for engineers, computer scientists, and developers. These ethical references **are to be integrated into the technology design process** (ethics by design / in design / for designers), ensuring the production of devices that guarantee patient-centeredness;
- encourage **responsible action with an awareness of the need to respect people's dignity, privacy, and safety;**
- take into consideration from the very beginning of the research and design process the foreseeable implications of technologies in the relational and social spheres;
- call for cooperation across disciplines to ensure safe, ethical and effective research and development;
- prepare ex ante **careful controls for the possible "training" of machines based on quality, up-to-date and interoperable data**; and conduct appropriate experiments in the area of robots (and AI) **to ensure safety and effectiveness** in the use of these new technologies;
- assume particular importance: **precaution, inclusion (transparency and participation), reversibility (of the sequence of operations performed), privacy (confidentiality and data protection);**
- include an ethics (and humanities) component during studies and training;
- involve expertise from advocacy and rights associations and potential patients in research and experimentation.

Indications for ethics committees for trials:
- **Ensure independence, transparency (verifiability of work) and speed of response;**
- integrate the figure of a computer scientist or AI expert and also update trial regulations with reference to software in clinical settings;
- **create public awareness in society regarding the opportunities and risks of new technologies**, so that citizens can participate critically in the debate on the use of robotic and digital technologies, avoiding both uncritical trust and exaggerated concern, aware of the choices and implications of digital health care: this promotion can also take place through the organization of conferences for schools and meetings with citizens;
- involving on issues not only physicians but also other experts with expertise in the specific area of discussion (e.g., disability condition, multicultural approaches, etc.).

C1.2.3 Legal liability.

● Ensure the **full compensation of the injured party** by simplifying the liability systems available to him or her so that access to justice and obtaining full compensation for the damage suffered is not excessively complex.
● Ensure a **proper distribution of liability for any damages** resulting from the use of these technologies, **including in the hands of the producers and developers of these technologies**. Consider the provision of related and appropriately commensurate insurance obligations.
● **Conceive a system of liability**, including through appropriate regulatory interventions, **that does not place a greater burden** - in law or in fact, taking into account the possible jurisprudential applications of the discipline - **on the physician or health professional who uses the technologies** in question than on those who, on the other hand, do not use them, thus avoiding the generation of defensive medicine mechanisms that may discourage the spread of these applications.
● To this end, **avoid the imposition of objective liability on the physician or health professional who decides to use** these technologies to treat appropriate cases.

C1.2.4 Product Standardization and Certification.
● Encourage **adequate training of technical personnel** called upon to develop rehabilitative robotic technologies **in the proper understanding of the applicable regulatory framework**, and in particular of **Regulation 2017/745**, including aspects of (1) certification and CE marking, (2) relevance and legal value of European standards, harmonized European standards, and international standards, and (3) the relationship between safety and liability regulations.
● Encourage adequate training on the same aspects also of the health care personnel called upon to use the aforementioned devices, especially with regard to the relevance of the intended use, the procedures for use, and the necessary training, in order to foster the proper understanding also of any liability profiles related to the misuse of the devices themselves.
● Encourage prompt reporting of any failures, malfunctions and accidents related to the use of the same devices, useful to monitor any risks not identified or otherwise not adequately considered during development and certification, taking advantage of the UDI system.

C1.2.5 Informed Consent
● **Information to the patient about the characteristics, risks, and expected benefits of robotic treatment must be given in a clear and understandable manner** in order to enable the patient to mature an informed decision. This information should also **highlight possible relevant differences from a conventional treatment, not assisted by similar applications.**
● **Explain the possibility of requesting from the patient** and ensuring **the presence of a person to monitor the progress during the course of the treatment.**

C1.2.6 Human relationship and machine interaction
Indications
Treatment of patients with robotic applications must never deprive them of a meaningful human relationship of care with the physician and health care personnel responsible for treatment. Indeed, patient care presupposes a relational dimension in the proper sense that can be given only with a human being and not with a machine.
● Treatment with robotic applications **must avoid** as far as possible inducing **a feeling of psychological or emotional distress,** that is, engendering a feeling of devalorization, whereby one feels isolated and undeserving of care and attention from a human being. The operator at the machine must therefore also have adequate training to reduce negative perceptions of the patient.
● In any case during treatment, **the presence of a competent operator must be ensured in a manner commensurate with the person's needs throughout the rehabilitation session.**
● The application must not be designed in such a way as to induce in the patient the misperception of the nature of a thing and not a living, animate or sentient being of the same.

● **The purpose of pursuing a pleasing and acceptable design on the part of the patient can under no circumstances justify its manipulation on a psychological and emotional level**, such as to induce him or her to anthropomorphize the machine, develop the false belief that it can be friendly, harbor a feeling or interest in his or her state of health and possible progress, thus inducing or fostering forms of attachment or dependence.

C1.3 What training paths/skills are recommended for practitioners?
Indications
- Considering teamwork as the most appropriate modality for the fruition of these technologies, the panel recommends **specific seminars that include health care and technical figures in** order to foster the appropriate clinical and engineering knowledge and allow, through shared if basic knowledge, optimal teamwork.
- it is suggested that **university master's degrees be implemented that also include the participation of manufacturing companies** so as to convey both specific knowledge about robotic rehabilitation and the transfer of that knowledge to devices actually present in rehabilitation facilities
- it is suggested that training also include relational, cultural and ethical aspects related to robotic devices.

Analysis of the documents produced by the working group revealed educational deficiencies related to robotic rehabilitation, which is offered in a "patchy" manner. The analysis seems to have been done substantially better with regard to undergraduate (first and second level) physical therapy courses. Specifically, the curricula of all these 40 degree programs were verified, and specific curricula of 15 were requested and obtained. This practice appears to have been done less extensively, for the occupational therapy degree program and the specialty of Physiatry.
The Jury agrees with the working group that it is not necessary to implement a single operator with specific training pathway for the application of robotic equipment.
Although there is no objective data, and literature to base its recommendations the jury strongly suggests the establishment of specific training moments within all relevant degree programs (Bachelor of Science in Physiotherapy, Occupational Therapy, Speech Therapy, Bachelor of Science in BioMedical Engineering and Medical Specialty of Physiatry), such as seminars and practical exercises.

PART THREE

Future perspectives and indications for research for robot-assisted rehabilitation
D1.1 What are the most promising development and research prospects and what recommendations would you provide for research?
The most promising future prospects should turn to the development of robotic devices in which the technical specifications of the devices themselves refer to existing theoretical models. Thus, **research should be directed not only toward measuring and quantifying motor recovery, but also toward ways of assessing the neurophysiopathological mechanisms induced by robot-mediated treatment.** Particular attention should be paid to the distinction between predominantly adaptive motor recovery and restoration of functions with characteristics as close as possible to physiological movement. For devices whose goal is not functional recovery but replacement of functions that can no longer be recovered, particular attention should be paid to better understanding the real benefits in terms of activity and participation.
In this framework it may also be recommended that **the equipment to be developed**, which in any case must respond to the above, **may be as easy to use and wear if necessary, of low cost, and capable of fostering an empathetic relationship with the person with disabilities**, as aspects albeit secondary but interesting for the dissemination of robotic equipment itself.

PARTICIPANTS

PROMOTING COMMITTEE

Paolo Boldrini - Società Italiana di Medicina Fisica e Riabilitativa (SIMFER)
Donatella Bonaiuti - Società Italiana di Medicina Fisica e Riabilitativa (SIMFER)
Stefano Mazzoleni - Società Italiana di Riabilitazione Neurologica (SIRN)
Federico Posteraro - Società Italiana di Riabilitazione Neurologica (SIRN)

ORGANIZATIONAL SEGRETARIAT

Guido Mondaini (Segreteria Nazionale SIMFER)

SCIENTIFIC TECHNICAL COMMITTEE

Paolo Benanti – Dipartimento di Teologia - Pontificia Università Gregoriana
Paolo Boldrini – Società Italiana di Medicina Fisica e Riabilitativa (SIMFER)
Donatella Bonaiuti - Società Italiana di Medicina Fisica e Riabilitativa (SIMFER)
Enrico Castelli - UOC di Neuroriabilitazione Pediatrica, Ospedale Bambino Gesú, Roma.
Francesco Draicchio - Istituto Nazionale Assicurazioni Infortuni sul lavoro (INAIL)
Vincenzo Falabella - FISH Onlus - Federazione Italiana per il Superamento dell'Handicap - FAIP Federazione Associazioni Italiane Paratetraplegici
Paolo Fogar – Federazione Nazionale Associazioni Trauma Cranico (FNATC)
Silvia Galeri - Dipartimento di Riabilitazione - Fondazione Don Carlo Gnocchi ONLUS - Centro "E. Spalenza" – ROVATO (BS)
Francesca Gimigliano - Dipartimento di Salute Mentale e Fisica e Medicina Preventiva, Università degli studi della Campania Luigi Vanvitelli – Cochrane Rehabilitation
Mauro Grigioni - Centro TISP - Centro nazionale tecnologie innovative in sanità pubblica – Istituto Superiore di Sanità
Stefano Mazzoleni – Dipartimento di Ingegneria Elettrica e dell'Informazione, Politecnico di Bari – Gruppo Nazionale Bioingegneria -Società Italiana di Riabilitazione Neurologica (SIRN)
Stefano Mazzon - UOC di Medicina Fisica e Riabilitativa - AULSS6 Euganea Padova - Distretto 4 "Alta Padovana"
Franco Molteni - UOC di Medicina Fisica e Riabilitativa - Ospedale Villa Beretta - Como
Giovanni Morone - Laboratorio Clinico di Neuroriabilitazione Sperimentale -IRCSS Fondazione Santa Lucia – Roma
Maurizio Petrarca - Laboratorio di robotica e analisi del movimento dell'ospedale pediatrico Bambino Gesù IRCSS Roma - GIS Fisioterapia Neurologica e Neuroscienze dell' Associazione Italiana FIsioterapia (AIFI)
Alessandro Picelli -Dipartimento Neuroscienze, Biomedicina e Movimento - Università di Verona
Federico Posteraro- Dipartimento di Riabilitazione AUSL Toscana Nord (CP)
Angelo Burini – CONFAPI Sanità
Michele Senatore- Associazione Italiana Terapisti Occupazionali (AITO)

Giuseppe Turchetti - Università Scuola Superiore di Sant'Anna - Istituto di Management

WORKING GROUPS

Working Groups 1 - Device classification
Coordinators:
Stefano Mazzoleni, Dipartimento di Ingegneria Elettrica e dell'Informazione, Politecnico di Bari – Gruppo Nazionale Bioingegneria - Società Italiana di Riabilitazione Neurologica (SIRN)
Marialuisa Gandolfi – Professore Associato – Medicina Fisica e Riabilitativa - Università di Verona
Components: Carla Daniele, Michela Goffredo, Matteo Malosio, Loris Pignolo, Loredana Zollo, Eugenio Guglielmelli, Nicola Petrone, Federico Posteraro; Jacopo Zenzeri, Daniele Munari, Giulia Sgubin, Elisa Gervasoni, Arianna Antonini.

Working Groups 2.1 - Developmental age
Coordinators:
Enrico Castelli -UOC di Neuroriabilitazione Pediatrica, Ospedale Bambino Gesú, Roma.
Donatella Saviola - Centro Cardinal Ferrari - Fontanellato (PR)
Components: Francesca Arduini, Elena Beretta, Emilia Biffi, Chiara di Pede, Francesca Gimigliano, Andrea Guzzetta, Martina Mandalà, Maurizio Nespoli, Claudia Pavarelli, Francesca Policastro, Marco Polverelli, Andrea Rossi, Giuseppina Sgandurra.

Working Groups 2.2 - Upper limb
Coordinators:
Giovanni Morone - Laboratorio Clinico di Neuroriabilitazione Sperimentale -IRCSS Fondazione Santa Lucia – Roma
Sofia Straudi - Dipartimento Neuroscienze e Riabilitazione - Azienda Ospedaliero Universitaria di Ferrara.
Components:
RCT Evidence in Stroke: Silvia Sterzi; Federica Bressi; Irene Aprile; Cristiano Pecchioli; Daniele Giansanti); Michela Agostini; Maria Luisa Gandolfi; Stefano Gargan; Sandra Miccinilli; Marco Bravi; Diletta Bruno; Fabio Santacaterina.
Systematic Reviews Stroke: Sofia Straudi; Chiara Arienti; Ludovica Baluardo.
Linee Guida: Giovanni Morone; Matteo Paci; Alex Martino Cinnera; Emanuela Casanova; Dario Marino; Giuseppe La Rosa; Angela Palomba; Alberto Battistini.
Evidenze in altre: Luca Perrero; Salvatore Petrozzino; Claudio Marcello Solaro; Serena Filoni; Monica Sicari; Manuela Desilvestri; Valentina Boetto; Emanuele Francesco Russo.

Working Groups 2.3 - Lower limb and gait
Coordinators:
Donatella Bonaiuti - Società Italiana di Medicina Fisica e Riabilitativa (SIMFER)
Davide Mazzoli - Gait and Motion Analysis Lab - Ospedale Sol et Salus- Rimini
Components: Elisa Andrenelli, Emiliana Bizzarrini, Anna Cassio, Salvatore Calabrò, Isabella Campanini, Simona Maria Carmignano, Simona Cerulli, Carmelo Chisari, Valentina Colombo, Stefania Dalise, Cira Fundarò, Valeria Gazzotti, Daniele Mazzoleni, Miryam Mazzucchell, Corrado Melegari, Andrea Merlo, Giulia Stampacchia.

Working Groups 2.4 - Balance
Coordinators:
Alessandro Picelli - Dipartimento Neuroscienze, Biomedicina e Movimento - Università di Verona
Thomas Bowman - Fondazione Don Carlo Gnocchi ONLUS - Milano
Components: Angelo Paolo Amico, Roberto Antenucci, Alessio Barichich, Luciano Bissolotti, Loredana Cavalli, Marianna Capecci, Giuseppina di Stefano, Perla Massai, Sandra Morelli, Antonio Nardone, Daniele Panzeri, Elisa Taglione, Johanna Jonsdottir.

Working Groups 3 - Theoretical reference models, future prospects, development and research

Coordinators: Franco Molteni, UOC di Medicina Fisica e Riabilitativa - Ospedale Villa Beretta - Como
Andrea Turolla - Laboratorio Tecnologie Riabilitative - San Camillo IRCSS - Venezia
Components: Mariele Colucci, Andrea Francesca Cecchi, Giovanni Cutti, Giuseppe D'Avenio, Francesco Draicchio, Salvatore Facciorusso, Roberto Gatti, Emanuele Gruppioni, Marco Iosa, Pawel Kiper, Deborah Mazzarotto, Rinaldo Sacchetti

Working Groups 4 – Organizational contexts
Coordinators:
Daniele Giansanti - Istituto Superiore di Sanità- Centro Nazionale Tecnologie Innovative in Sanità Pubblica
Irene Aprile - Dipartimento di Riabilitazione Neuromotoria - Fondazione Don Gnocchi ONLUS - Roma
Components: Angelo Burini, Antonio Bortone, Gabriella Casu, Giovanni Antonio Checchia,Baldo Ippolito, Andrea Montis, Pamela Salucci, Antonio Robecchi Majnardi, Andrea Santamato, Giovanni Taveggia, Giuseppe Turchetti.

Working Groups 5 – Training paths/competencies for operators
Coordinators:
Silvia Galeri- Dipartimento di Riabilitazione - Fondazione Don Carlo Gnocchi ONLUS - Centro "E. Spalenza" – Rovato (BS)
Susanna Mezzarobba - Dipartimento di Neuroscienze, riabilitazione, oftalmologia, genetica e scienze materno-infantili- Università di Genova
Components: Michelangelo Bartolo, Gabriella Casu, Raffaella Gaeta, Pietro Marano, Stefano Masiero, Giuseppe Massazza, Mauro Zampolini.

Working Groups 6 - Regulatory, ethical and social aspects
Coordinators:
Sandra Morelli - Istituto Superiore di Sanità
Paolo Boldrini - Società Italiana di Medicina Fisica e Riabilitativa (SIMFER)
Components: Arianna Antonini- Marco Baccini; Laura Beccani; Maria Consiglia Calabrese; Antonio de Tanti; Vincenzo Falabella; Cira Fundarò; Daniele Giansanti; Paola Meli.

JURY

- Alessandro Ghirardini (Jury President)- Istituto Superiore di Sanità
- Andrea Bertolini- Scuola Superiore Sant'Anna di Pisa
- Maria Chiara Carrozza - Scuola Superiore Sant'Anna di Pisa
- Carlo Casalone - Pontificia Accademia per la Vita
- Davide Cattaneo - Associazione Italiana Fisioterapia (AIFI) e Università di Milano
- Francesco Della Gatta - Associazione Italiana Fisioterapia (AIFI)
- Pietro Fiore - Società Italiana di Medicina Fisica e Riabilitativa (SIMFER)
- Alessandro Giustini - Ospedale Riabilitativo San Pancarazio - Arco di Trento (TN)
- Simone Cecchetto - Associazione Italiana di Fisioterapia (AIFI)
- Marco Franceschini - IRCSS San Raffaele - Roma
- Giampiero Griffo - Federazione Italiana per il Superamento dell''Handicap (FISH)
- Stefano Paolucci - Società Italiana di Riabilitazione Neurologica (SIRN)
- Christian Parone - Associazione Italiana Terapisti Occupazionali (AITO)
- Massimo Pulin - CONFIMI Sanità
- Mauro Ricca - ASTT degli Spedali Civili - Brescia
- Maria Luisa Scattoni - Istituto Superiore di Sanità
- Nicola Smania – Dipartimento Neuroscienze, Biomedicina e Movimento - Università di Verona
- Nicola Vanacore - Istituto Superiore di Sanità

JURY WRITING COMMITTEE
Alessandro Ghirardini, Davide Cattaneo, Simone Cecchetto, Alessandro Giustini, Mauro Ricca, Maria Luisa Scattoni, Nicola Smania