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Evidence-informed and consensus-based statements about SAFEty of Physical Agent Modalities Practice in physiotherapy and rehabilitation medicine (SAFE PAMP): a national Delphi of healthcare scientific societies

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ABSTRACT

Objective A shared consensus on the safety about physical agent modalities (PAMs) practice in physiotherapy and rehabilitation is lacking. We aimed to develop evidence-informed and consensus-based statements about the safety of PAMs.

Study design and setting A RAND-modified Delphi Rounds' survey was used to reach a consensus. We established a steering committee of the Italian Association of Physiotherapy (Associazione Italiana di Fisioterapia) to identify areas and questions for developing statements about the safety of the most commonly used PAMs in physiotherapy and rehabilitation. We invited 28 National Scientific and Technical Societies, including forensics and lay members, as a multidisciplinary and multiprofessional panel of experts to evaluate the nine proposed statements and formulate additional inputs. The level of agreement was measured using a 9-point Likert scale, with consensus in the Delphi Rounds assessed using the rating proportion with a threshold of 75%.

Results Overall, 17 (61%) out of 28 scientific and technical societies participated, involving their most representative members. The panel of experts mainly consisted of clinicians (88%) with expertise in musculoskeletal (47%), pelvic floor (24%), neurological (18%) and lymphatic (6%) disorders with a median experience of 30 years (IQR=17–36). Two Delphi rounds were necessary to reach a consensus. The final approved criteria list comprised nine statements about the safety of nine PAMs (ie, electrical stimulation neuromodulation, extracorporeal shock wave therapy, laser therapy, electromagnetic therapy, diathermy, hot thermal agents, cryotherapy and therapeutic ultrasound) in adult patients with a general note about populations subgroups.

Conclusions The resulting consensus-based statements inform patients, healthcare professionals and policy-makers regarding the safe application of PAMs in physiotherapy and rehabilitation practice. Future research is needed to extend this consensus on paediatric and frail populations, such as immunocompromised patients.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Starting from a recent scoping review of the literature, we aimed to acknowledge evidence-informed indications of rehabilitation for safe physical agent modalities (PAMs).
⇒ Indications on the safety of physical agents (PAMs) were developed by a steering committee for different target conditions in physiotherapy and rehabilitation practice and supported by evidence and clinical expertise.
⇒ We strictly followed published guidelines for reporting and conduction, with a priori publicly registered protocol to determine agreement within the Delphi process.
⇒ The multiprofessional and multidisciplinary panel of experts rated and revised the agreement of indications for safe PAMs rehabilitation in multiple rounds until reaching a consensus.
⇒ Indications did not cover the clinical effectiveness of PAMs as well as specific subgroups for which evidence and expertise were not available.

INTRODUCTION

Physical agent modalities (PAMs) are extensively applied in physiotherapy and rehabilitation practice by targeting tissues to reduce swelling, alleviate pain, enhance healing and improve muscle tone.[1–4] These treatments, recommended and administered by healthcare professionals across various medical fields, are often integrated with

other physiotherapy and rehabilitation interventions.[5] However, ensuring the safety of these treatments is fundamental for both clinicians and patients. Previous consensus on contraindications and precautions associated with using PAMs from various organisations was released in the early 2000s.[6–8] Still, they have become outdated in light of technological advancements of the last years.[9 10] A recent scoping review of the literature[5] examined several systematic reviews on the safety of commonly used PAMs. This scoping review, encompassing treatments such as cryotherapy, electrical stimulation, transcutaneous electrical nerve stimulation, functional electrical stimulation, extracorporeal shockwave therapy, laser therapy, magnetotherapy, pulsed electromagnetic field and diathermy, revealed no important harm associated with their use. Nevertheless, it is worth noting that adverse events may be under-reported in primary studies[11 12] highlighting the need to integrate expert experience to bridge the current gaps between existing literature and clinical practice. Therefore, the purpose of the SAFEty of Physical Agent Modalities Practice (SAFE PAMP) consensus in physiotherapy and rehabilitation is to develop evidence-informed and expert consensus-based statements about the safety of PAMs through a RAND Delphi procedure. Our goal is to make patients, healthcare professionals and policymakers aware about the safe application of PAMs in physiotherapy and rehabilitation.

METHODS

Design

A RAND-modified Delphi Rounds survey process was employed as the facilitation technique for reaching expert consensus.[13 14] The Delphi technique is primarily used when the available knowledge is incomplete or subject to uncertainty.[15] We followed the guidance on 'Conducting and REporting of DElphi Studies'.[16 17 18] More details are reported in online supplemental file 1. The protocol was a priori registered on the Open Science Framework online repository.[19]

The process consisted of four phases: (1) establishment of the steering committee and invitation of national scientific and technical societies to constitute the panel of experts; (2) generation of statements using a comprehensive approach based on a published scoping review of existing systematic reviews on PAMs safety in physiotherapy and rehabilitation medicine[5] as well as on expertise from content experts of the steering committee; (3) rating of statements from the panel of experts through a national Delphi survey aiming to identify, assess and modify statement importance for each field (eg, musculoskeletal) and (4) an online workshop meeting to finalise the list of statements reaching the final consensus. Finally, we planned to disseminate the final statements list as good clinical practice (figure 1).

Phase I: establishment of the steering committee and panel of experts

Steering committee

In June 2022, the project team nominated a steering committee responsible for defining the list of statements of safe PAMs, selecting national scientific and technical societies for expert participants, developing the Delphi questionnaires, and analysing responses from participants after each round.

The steering committee involved 11 content experts from the Italian Association of Physiotherapy (Associazione Italiana di Fisioterapia (AIFI)), a member of the World Physiotherapy.[20] AIFI is the scientific and technical society in Italy for the physiotherapy profession recognised by the Italian Minister of Health to produce clinical practice guidelines in the field.[21 22]

To assure the external validity of the consensus process, the steering committee included two content experts on PAMs (MB and EP), three on rehabilitation of musculoskeletal disorders (GR, VG and SB), one on neurological physiotherapy and neuroscience (AT), one on pelvic floor rehabilitation (AF) and four methodologists (SGambazza, SGianola, GC and LP).

Panel of experts

It is known that the diversity of a Delphi panel has an impact on the quality of the final recommendations. In contrast, no agreement on the panel size for Delphi studies exists. Panels of 20–30 participants are common.[23 24] Thus, the steering committee invited all the national multidisciplinary and multiprofessional scientific and technical societies involved in physiotherapy and rehabilitation care (n=26) and the societies dealing with forensics (n=1). These societies were identified from the published endorsed by the Italian Ministry of Health and are recognised as the ones entitled to generate national clinical practice guidelines.[21 22] Each society delegated their most representative member involved in physiotherapy and rehabilitation care to join the panel of experts. The panel of expert members was multidisciplinary and multiprofessional, including clinicians, researchers and healthcare managers from different fields[24] (eg, orthopaedics, neurology). To represent patients' perspectives, the panel also included a lay member from Cittadinanzattiva,[25] the largest Italian patient advocate organisation that promotes citizen activism for the protection of rights, the care of common goods and support for people in conditions of weakness.

Phase II: generation of statements

First, the steering committee formulated statements aimed at safety based on evidence and clinical expertise. Particularly, evidence was summarised from a published scoping review and its online supplemental materials,[5] which gathered information about the safety of the nine PAMs from 117 systematic reviews in physiotherapy and rehabilitation medicine (eg, safety of PAMs for low back pain, osteoarthritis, stroke, urinary incomitance). Clinical

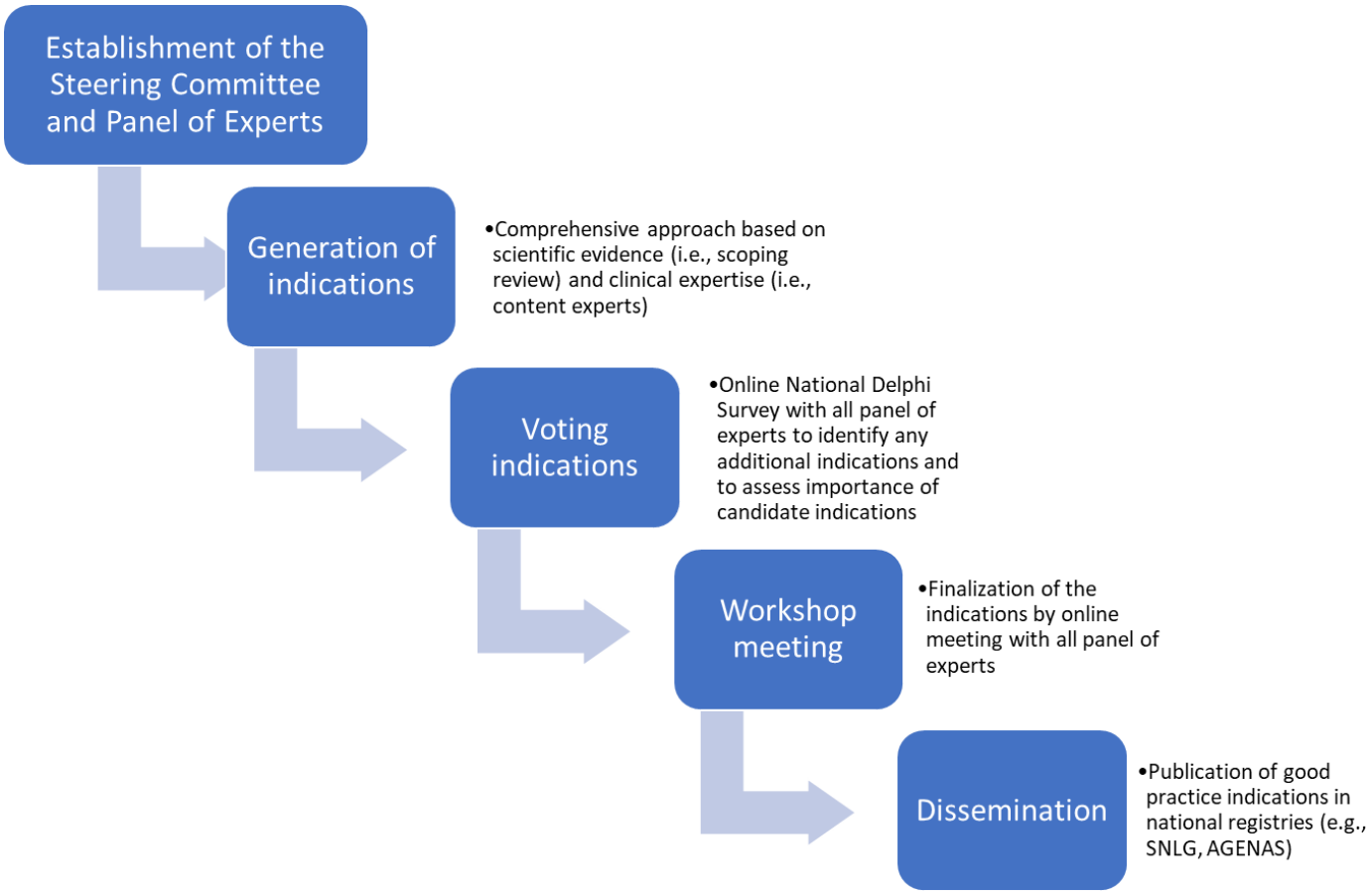

Figure 1 Phases of the RAND Delphi process. Legend: SNLG, Sistema Nazionale Linee Guida; AGENAS, Agenzia nazionale per i servizi sanitari regionali

expertise was assured by content experts of AIFI (eg, musculoskeletal disorders, orthopaedic and neurological physiotherapy and pelvic floor rehabilitation) adding examples of clinical conditions for which they commonly safely apply PAMs in their specific field. Disagreements between experts were resolved through discussion.

The steering committee formulated statements for each PAM (with distinction of evidence and expertise) ensuring that all the potentially relevant topics in the field would be included in the initial list of questions for the first Delphi round (online supplemental file 2 reported details about each included PAM). Each statement included a statement regarding safety about the following PAMs:

1. Electrical stimulation.
2. Neuromodulation, antalgic and interferential electrical currents.
3. Extracorporeal shock wave therapy.
4. Laser therapy.
5. Electromagnetic therapy.
6. Diathermy.
7. Hot thermal agents.
8. Cryotherapy.
9. Therapeutic ultrasound.

Statements were developed for different target conditions. PAMs are delivered by expert healthcare professionals (who had undergone formal education and training) to ensure patient safety in inpatient and outpatient settings. Statements were presented within the relevant rehabilitation field, along with a list of patient conditions in which the PAMs were indicated as safe and supported by evidence and clinical expertise.

Phase III: rating of statements through Delphi rounds

We employed an electronic Delphi process, allowing participants to submit responses anonymously and independently without being biased by other participants' identities and responses. The steering committee reached out to the panel of experts using the SurveyMonkey online platform (Palo Alto, California, USA; www.surveymonkey.com) and used a blinded electronic rating.

The web-based survey comprised two sections: the first concerned the participants' demographics (eg, type of profession, field of expertise and years of experience), and the second involved rating the statements. The panel of experts evaluated the proposed statements and provided additional comments using a free text box to ensure complete coverage of the topics. According to the RAND method, the panel of experts used a 9-point Likert scale (ie, 1–3=highly inappropriate, 4–6=undecided and 7–9=highly appropriate) to rate the level of concordance for each statement.

In addition, experts could abstain from rating by selecting the answer 'not my expertise' for statements they were not familiar with.

A summary of results for each Delphi round was shared as feedback to update panel members on the progress of consensus development, including descriptive statistics, to guide subsequent rounds. The panel of experts was asked to re-rate their evaluation in subsequent rounds only for those statements needing clarification or for statements for which consensus (ie, ≥75% on a 7–9 points scale or 1–3 points scale) was not reached.

An anonymous report of each round was provided to each expert, showing the distribution of responses for each statement, along with all additional comments provided in the free text box. Based on previous ratings, statements were modified and presented for the next round. Up to three reminder emails for completion were sent to each participant individually. Data collection occurred over 5 months (June–November 2022).

Phase IV: workshop meeting as last round

After reaching a consensus, the steering committee joined an online meeting to refine statements according to each expert's contribution and confirm which statements would be included in the final criteria list. Finally, the panel of experts was asked to rate the final statements list for the closing audit procedure.

Definition and calculation of consensus

In agreement with the RAND appropriateness method, we adopted predefined criteria[26] to assess the consensus in the Delphi method, using the proportion of ratings with a threshold of 75%.[27] Specifically:

1. Consensus in: ≥75% of participants scored the item as 'highly appropriate' (scores 7–9) and<15% scored the item as of 'highly inappropriate' (scores 1–3).
2. Consensus out: ≥75% of participants scored the item as of 'highly inappropriate' (scores 1–3) and<15% scored the item as 'highly appropriate' (scores 7–9).
3. No consensus: all other results.

Statistical analysis

Descriptive statistics were used to describe general characteristics of participants, summarised as median and IQR and counts and percentage (%), as appropriate. Each statement was analysed quantitatively by the percentage of agreement ratings.

Role of the funding source

AIFI supported this research. The funder played no role in this study's design, conduct or reporting.

Patient and public involvement

In this study, a patient representative participated in the panel of experts to rate the statements.

RESULTS

Participants

Out of the 28 scientific and technical societies/organisations that were invited as panel of experts, 2 declined their interest in participation, while 9 did not provide a response. Finally, 17 societies/organisations (invitation rate: 61%), each represented by their most representative expert member, were included (figure 2). The majority of experts were clinicians (88.2%), with half having expertise in musculoskeletal disorders (47.1%). Others were specialised in areas such as pelvic floor (23.5%), neurological (17.6%), lymphatic disorders (5.9%), paediatrics (5.9%). The panel also included a forensic and a lay member as patient representative. On average, experts had a median of 30 years of experience (IQR 17–36) in their respective fields. All general characteristics are reported in table 1. No conflict of interest was present (online supplemental file 3).

Delphi rounds

Two Delphi rounds were necessary to reach a consensus.

Round 1

Overall, 17 experts panel participants completed the survey (participation rate: 100%). All statements passed the first round with a consensus of 75% (table 2). Five experts offered justifications for their choices (eg, examples of clinical practice) and provided important inputs for the statements. In particular, most of them raised concerns about the safe use of PAMs in children. Additionally, they suggested refining the purpose of the statements, emphasising that the focus was on patient safety rather than provider safety. Some experts reported uncertainties about safe use of PAMs based on their experiences. For example, one expert mentioned the possibility of mild skin irritation in hot thermal therapies, and another suggested caution in the use of cryotherapy due to risk of cold burns, especially if patients are not well informed or supervised. Then, one expert expressed uncertainty about the safety of long-term use of electromagnetic therapies. Some experts suggested the safe use of PAMs in other fields of applications such as the use of diathermia in the dermatology for lichen sclerosus, which was out of our purposes. All comments were considered in the release of the statements (online supplemental file 4).

Round 2

The statements from round 1 were reviewed based on panel comments for the subsequent assessment in round 2, with a specific restriction on the adult population and a clearer emphasis on patient safety.

In round 2, a total of 14 expert panel participants completed the survey (participation rate: 82%), and all the statements achieved consensus out of the 75% threshold (table 2). One expert provided additional comments including examples of expertise, which were subsequently integrated into the final list of statements.

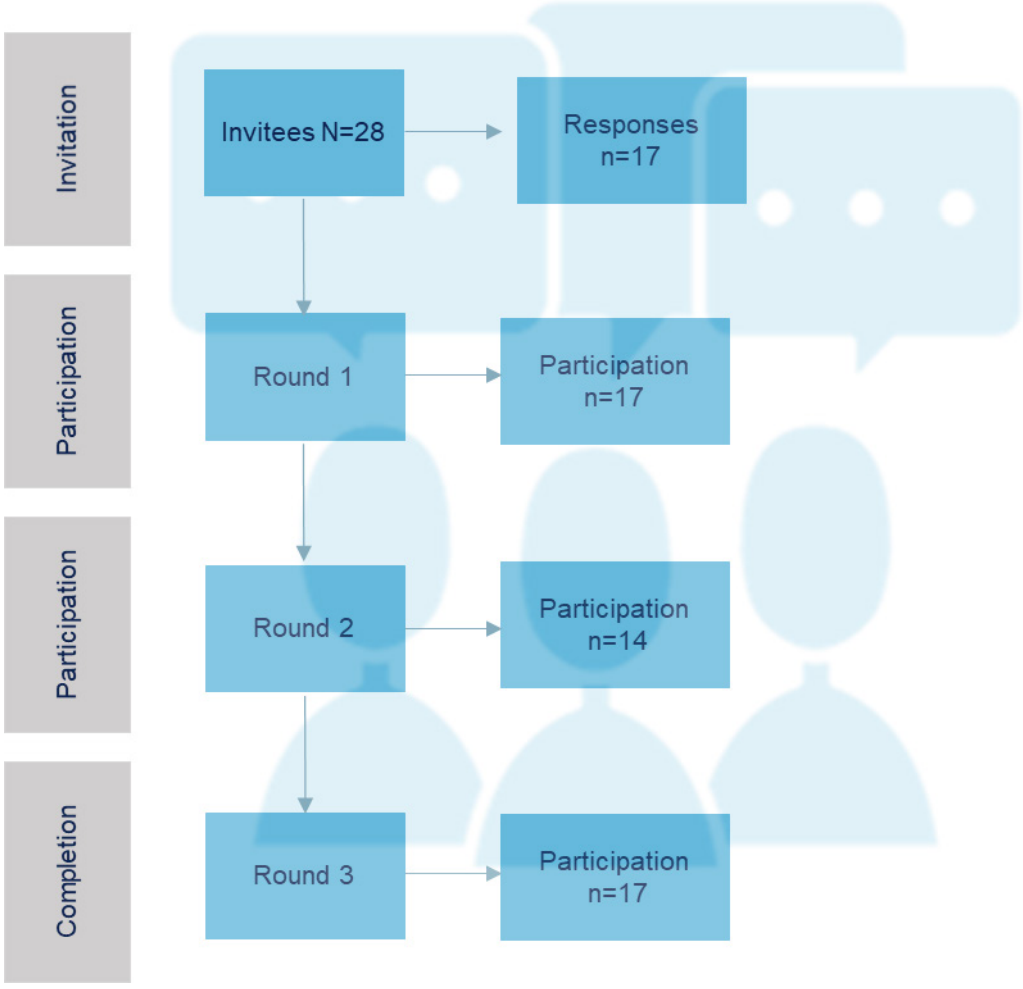

Figure 2 Flow chart of Delphi process.

In particular, low-level laser therapy could exacerbate genital dryness, necessitating additional interventions to improve hydration during the treatment period and mitigate discomfort for patients. Additionally, there was uncertainty regarding the application of other therapies, such as electrical stimulation and extracorporeal shock wave therapy, in certain fields due to limited expertise (online supplemental file 4).

Table 1 General characteristics of experts panel (n=17)

Professional profile*	Responses N (%)
Clinicians	15 (88.2)
Researchers	7 (41.2)
Management	4 (23.5)
Field of expertise*	
Musculoskeletal	8 (47.1)
Pelvic floor disorders	4 (23.5)
Neurological	3 (17.6)
Lymphatic disorders	1 (5.9)
Paediatrics	1 (5.9)
Lay member (patient)	1 (5.9)
Forensic member	1 (5.9)

*More than one answer was possible.

Workshop meeting

On 27 September 2022, nine experts panel participants (completion rate: 53%) joined the online meeting to discuss comments, justifications and highlights. A comprehensive digital presentation of the findings from round 1 and round 2 were reported during the workshop. During the meeting, the panel of experts suggested introducing a general note explicitly stating that statements on safety were not extended to different subgroups of the population (eg, children, adolescents, immunocompromised individuals) due to lack of literature.

The final list of statements, along with this general note, was shared via SurveyMonkey for final approval. All 17 experts panel participants (approval rate: 100%) approved and released the final list of statements. One expert selected the option 'not my expertise' for the

Table 2 Agreement results for each round

Statements about the safety of…	Round 1		Round 2		Final list	
	Percentage of agreement (7–9 points on the Likert scale)	Percentage of disagreement (1–3 points on the Likert scale)	Percentage of agreement (7–9 points on the Likert scale)	Percentage of disagreement (1–3 points on the Likert scale)	Approved	NME
Electrical stimulation	85.7	7.1	85.7	0.0	100.0	0.0
Neuromodulation, antalgic and interferential electrical currents	100.0	0.0	100.0	0.0	100.0	0.0
Extracorporeal shock wave therapy	83.3	0.0	76.9	0.0	100.0	0.0
Laser therapy	84.6	7.7	90.9	0.0	100.0	0.0
Electromagnetic therapy	81.8	9.1	76.9	0.0	100.0	0.0
Diathermy	90.0	10.0	84.6	0.0	100.0	0.0
Hot thermal agents	81.8	9.1	91.7	0.0	100.0	0.0
Cryotherapy	75.0	0.0	90.9	0.0	94.2	5.8
Therapeutic ultrasound	90.9	0.0	91.7	0.0	100.0	0.0
General note*	–	–	–	–	100.0	0.0

*Added for the final criteria list.
NME, not my expertise.

statement on cryotherapy (table 2). In online supplemental appendix 1, we reported the final criteria list released for good clinical practice with details of sources (evidence and expertise) and applications in different fields and clinical conditions.

DISCUSSION

Main findings

The SAFE PAMP consensus developed safety statements for PAMs in physical therapy and rehabilitation practice. The multidisciplinary and multiprofessional panel of experts participated with a moderate response rate (61%).[28] All nine statements were approved in two rounds (consensus of over 75% agreement.) and released in a final workshop meeting with some adjustments made (eg, specific population subgroups). In summary, experts agreed on the safety of PAMs in the adult population (>18 years) when prescribed and applied by a healthcare professional (eg, physiotherapist, physician) who is adequately trained and informed, as required by education and licensure.

Literature context

Earlier consensus documents from different organisations were published in 2001,[6] 2006[7] and 2010.[8] In 2018, the American Occupational Therapy Association issued a position paper[29] clarifying the appropriate use of PAMs in contemporary occupation-based occupational therapy practice, providing clinical case vignettes in their field. Others reported indications and contraindications about specific types of PAMs (eg, extracorporeal shock wave therapy[30]). Many other societies, such as National Institute for Clinical Excellence, also offer specific clinical questions guidelines, and we cannot exclude that they can involve recommendations on PAMs (eg, NG59 for low back pain[31]).

Overall, the Canadian document[8] represents the most comprehensive guidance on this topic. However, our Delphi is the most recent consensus on PAMs focusing on statements about safe PAMs application as clinical practice indications (eg, field) sustained by literature and clinical expertise. This does not mean that the contraindications and precautions mentioned in the Canadian guideline[8] are in contrast to our findings. Simply, we use a complementary perspective. Our Delphi agrees to define the common safe applications stratifying by fields/conditions whereas the Canadian one describes the contraindications and precautions about these common applications in particular situations or under certain circumstances. For instance, both documents recognise cryotherapy and electrical stimulation as commonly safe PAMs in musculoskeletal applications, such as treating ankle sprains and osteoarthritis. However, the Canadian guideline recommends precaution when combining compression with cryotherapy to ensure the preservation of circulation and nerves. Furthermore, the guideline contraindicated the use of electrical stimulation in presence of implanted electronic devices. Although the evidence presented in the Canadian guideline was not systematically collected (Canada and the US experts in conjunction with multiple sources such as textbooks), it is reasonable to assume that many precautions and contraindications still remain applicable. Nevertheless, it is important to note that guidelines should be updated every 3–5 years or when new information becomes available.[32 33]

Implications for clinicians

Healthcare professionals are encouraged to use a comprehensive approach when using this Delphi consensus.

Prior to proposing PAMs to patients, they must collect their medical history (eg, comorbidities) to better determine the diagnosis, prognosis, anticipated goals and expected outcomes.[34] Then, they should incorporate the best research evidence, clinical expertise, patient values, needs and preferences to propose effective treatments, balancing effectiveness and safety. It is imperative that patients are informed about the possibility of trivial adverse events (eg, pain and erythema at the application site[5] using extracorporeal shock wave therapy). However, in situations when evidence is lacking and there is a likelihood of moderate to severe harm, caution is advised, and the use of PAM may be reconsidered. In fact, for precautionary reasons,[35–37] the developed statements were not generally extended to other subgroups, such as children and adolescents (due to biological tissue in growth phases[38 39]), and frail individuals (eg, immunocompromised patients), given the limited and insufficient literature on potential harm. It is important to adhere to these statements in conjunction with precautions and contraindications under specific circumstances, referring to equipment manufacturers' manuals and regulatory bodies[40] as well as previous guidelines[8] and standards established by professional associations.

Implications for stakeholders

Good practices for patients safety should be managed by national agencies with a living monitoring system and shared through international initiatives such as the WHO Global Patient Safety Challenge Medication Safety[41] to enhance systems and practices adopting corrective action within countries. For instance, national and international scientific and technical societies should facilitate the dissemination of CPGs through various strategies, such as storing good clinical practices in shared repository[42] as well as disseminating plain, patient-oriented versions of good clinical practice statements. This supports patient empowerment and contributes to making the healthcare system more efficient, tailored and safer.[43 44] We plan to organise meetings with stakeholders and patients, conduct webinars and provide education and counselling through pamphlets, videos and social media messages.

Implications for research

We believe that the statements developed by the multidisciplinary and multiprofessionally panel of experts can be generalised worldwide. These results could provide essential information to produce national guidelines (eg, Good Clinical Practices of the Italian Ministry of Health[45]) and international guidelines to improve patient safety and decrease avoidable harm related to interventions. Studies should convey their efforts to plan and adequately report adverse events before objectively estimating these harms. We call for multicentric randomised controlled trials based on a core outcome set, including harms in addition to benefits.[46] In addition, specific subgroups of populations should be studied. It is a serious matter to exclude a group from research eligibility, and this should only be done when no less restrictive option is sufficient to ensure protection from undue risk.[47]

Lastly, future studies can better expand our statements to ensure the safest and most optimal modality application of the proposed PAMs (eg, optimal voltage, amperage, frequency, current density, dose), as well as contraindications and precautions, especially for the mentioned subgroups (eg, children, immunocompromised individuals).[48]

Strength and limitations

This represents the first effort to provide guidance on the safety of PAMs in physiotherapy and rehabilitation. We strictly followed published guidelines for reporting and conduction. In addition, we a priori publicly registered the consensus criterion used to determine agreement within the Delphi process.[26 49] We adopted one of the most conservative thresholds for obtaining the consensus (75%),[27] and in all rounds, this threshold was reached with a high percentage of agreements. However, some downsides should be acknowledged. We did not cover statements about the clinical effectiveness of PAMs, as our aim was to make patients, healthcare providers and policy-makers aware about the safety application of PAMs in clinical practice. As well, we did not aim to report specific contraindications as we started collecting evidence from systematic reviews that reported safety outcomes from primary studies, which may not always encompass real-world conditions, such as the presence of comorbidities (eg, active deep vein thrombosis). Furthermore, evidence informed by systematic reviews did not find enough information about the risk for specific population (eg, haemato-oncological patients with severe immunocompromised or coagulopathy). However, based on the principle of precaution, the panel agreed to add as a general note about precautions in specific subgroups of the population, in the absence of literature. As with all Delphi process, our study relies on national expert response and may not capture the full range of perspectives or experiences.[16 50] Nevertheless, we tried to involve multidisciplinary and multiprofessional experts (as occurs in clinical practice guidelines) enabling confrontations in anonymity (avoiding negatively influencing outcomes and encouraging balanced consideration of ideas). Then, statements were developed starting from the scoping review,[5] which mapped and summarised safety in population and intervention areas without assessing the certainty of evidence (eg, grading of the certainty of evidence).[5] Lastly, even though we generated statements based on the latest available evidence, we should recognise that adverse events may be underestimated since safety outcome is commonly poorly reported in the literature.[11 12 51]

CONCLUSION

These evidence-based statements inform patients, healthcare professionals and policy-makers about the safety of a wide range of PAMs in various fields and conditions

of physiotherapy and rehabilitation practice, following comprehensive clinical evaluation of patients' needs. All of these statements should be associated to precautions and contraindications for specific cases, referring to previous guidelines, equipment manufacturers' manual and regulatory bodies. This consensus can provide a basis for decision-making and future research.

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Appendix 1. Final criteria list

Introduction

The statements are focused on the adult population. Each statement was developed based on the scientific literature (i.e., evidence) and the experience of content experts from the Associazione Italiana di Fisioterapia - AIFI (i.e., expertise) with details for clinical conditions in the relevant rehabilitation fields.

Target group: statements were developed for adults (> 18 years). Physical agents modalities (PAMs) are delivered by expert healthcare professionals (who had undergone formal education and training) to ensure patient safety in both inpatient and outpatient settings.

Conditions of application: statements were presented within the relevant rehabilitation field according to *informed-evidence* and *expertise-based* consensus.

Evidence: this section has been defined based on a scoping review of the literature conducted by two independent reviewers focusing on the safety of PAMs from 117 systematic reviews in physiotherapy and rehabilitation medicine (5).

Expertise: this section has been formulated by the steering committee, which included different content experts from AIFI (e.g., neurological, musculoskeletal, pelvic floor, physical therapies), with additional inputs from the multidisciplinary and multi-professional panel of experts.

Final list of statements

1. Electrical stimulation (e.g., Functional electrical stimulation (FES), Neuromuscular electrical stimulation (NMES), Electrical muscle stimulation (EMS)) is safe in the adult population

- in musculoskeletal disorders, especially in the following conditions:

o Evidence: neck pain, knee osteoarthritis, musculoskeletal pain, muscle hypotrophy.

o Expertise: spinal osteoarthritis, knee osteoarthritis, musculoskeletal pain, knee osteoarthritis, muscle and joint pain.

- in pelvis-perineal disorders, especially in the following conditions:

o Evidence: urinary incontinence, fecal incontinence, lower urinary tract symptoms in postpartum women, overactive bladder.

o Expertise: prolapse, descending perineum syndrome, perineal hypotonia, bladder-sphincter or anorectal dyssynergia, erectile dysfunction, premature ejaculation, abdominal diastasis.

- in neurological disorders, especially in the following conditions:

o Evidence: migraine, spasticity in multiple sclerosis, stroke, spinal cord injury.

o Expertise: post-stroke urinary incontinence, neurogenic bowel dysfunction in spinal cord injury, second motor neuron disease (e.g., Amyotrophic Lateral Sclerosis), muscular dystrophies, head trauma, lesions of the peripheral nervous system.

2. Neuromodulation, antalgic and interferential electrical currents (e.g., TransCutaneous Electrical Nerve Stimulation (TENS), Transcutaneous Tibialis Posterior Stimulation (TTNS)) are safe in the adult population

- in musculoskeletal disorders, especially in the following conditions:

o Evidence: low back pain, neck pain, rotator cuff disease, whiplash-associated disorders, fibromyalgia.

o Expertise: musculoskeletal pain, spine osteoarthritis, neuropathic pain.

- in pelvis-perineal disorders, especially in the following conditions:

o Evidence: overactive bladder, urinary incontinence, fecal incontinence, persistent pelvic pain.

o Expertise: Urinary incontinence, pudendal neuralgia, constipation, urinary retention.

- in neurological disorders, especially in the following conditions:

o Evidence: neuropathic pain, stroke, multiple sclerosis, neurogenic bowel dysfunction after spinal cord injury.

o Expertise: neurogenic bladder dysfunction after central and peripheral nervous system injuries.

3. Extracorporeal shock wave therapy (radial and focal) is safe in the adult population

- in musculoskeletal disorders, especially in the following conditions:

o Evidence: soft tissue disorders of the lower limbs, knee tendinopathy, Achilles tendinopathy, osteoarthritis, plantar fasciitis, rotator cuff disease, shoulder tendinopathy and

calcifications, acute fracture, orthopedic disorders, consolidation delays, other soft tissue disorders.

o Expertise: enthesopathies of the upper and lower limbs, calcifications, epicondylitis, epitrocleitis, muscle injuries, muscle contractures, and trigger points.

- in neurological disorders, especially in the following conditions:

o Evidence: post-stroke lower limb spasticity, multiple sclerosis spasticity.

o Expertise: spasticity following head trauma, spasticity following spinal cord injury.

- in pelvis-perineal disorders, especially in the following conditions:

o Evidence: chronic prostatitis/chronic pelvic pain syndrome.

o Expertise: persistent female pelvic pain, Peronye's disease.

Patients should be informed of the potential undesirable effects following the application of extracorporeal shock wave therapy. Indeed, a recent literature review showed some expected mild adverse events, such as pain and erythema, at the application site.(5)

4. Laser therapy (e.g., low-level laser therapy (LLLT), high-level laser therapy (HLLT)) is safe in the adult population

- in musculoskeletal disorders, especially in the following conditions:

o Evidence: low back pain, Achilles tendinopathy, rotator cuff disease, capsulitis adhesive, lower extremity soft tissue disorders, frozen shoulder, carpal tunnel syndrome, knee osteoarthritis, neck pain, whiplash associated disorders.

o Expertise: upper and lower limb tendinopathy, acute arthropathy, acute muscle and tendon injuries, acute musculoskeletal pain. Upper and lower limb tendinopathy, acute arthropathy, acute muscle and tendon injury, and acute musculoskeletal pain.

- *in pelvis-perineal disorders (extracavitary LLLT only), especially in the following conditions:*

o Evidence: Urinary incontinence and pelvic organ prolapse, persistent pelvic pain.

o Expertise: healing (episiotomies, laparotomies, lacerations, etc.), inflammatory pelvic pain, edema or perineal hematomas.

- *in lymphatic disorders* (LLLT only), especially in the following conditions:

o Evidence: secondary lymphoedema (e.g., breast cancer-related lymphedema).

o Expertise: lymphoedema

- *in neurological disorders (LLLT only), especially in the following conditions:*

o Evidence: Bell's palsy

o Expertise: stroke, multiple sclerosis, spinal cord injury, head trauma, peripheral nerve injury.

5. Electromagnetic therapy (e.g., Pulsed ElectroMagnetic Field Therapy (PEMFT), repetitive Peripheral Magnetic Stimulation (rPMS)) is safe in the adult population

- *in musculoskeletal disorders, especially in the following conditions:*

o Evidence: neck pain, fractures, consolidation delays.

o Expertise: osteoporosis, bone edema, algodystrophy, arthrosis.

- in pelvis-perineal disorders, especially in the following conditions:

o Evidence: persistent pelvic pain and urinary incontinence.

o Expertise: fecal incontinence, prolapse, descending perineum syndrome, perineal hypotonia, vescico-sphincteric or anorectal dyssynergia, pudendal neuralgia, pelvic pain acute, erectile dysfunction, premature ejaculation, diastasis recti.

6. Diathermy (e.g., Short Wave Tecar Therapy) is safe in the adult population

- in musculoskeletal disorders, especially in the following conditions:

o Evidence: rotator cuff disease, knee osteoarthritis.

o Expertise: sub-acute/persistent muscle injuries, DOMS/DOMER, arthropathies (non-acute), osteoarthritis, muscle contractures, trigger points.

- in pelvis-perineal disorders, especially in the following conditions:

o Evidence: inflammatory pelvic pain, persistent pelvic pain, sexual dysfunction (Peronye's disease).

o Expertise: prolapse, stress urinary incontinence, scarring (episiotomies, laparotomies, lacerations, etc.), perineal edema or hematoma, vulvovaginal dystrophy and dryness, abdominal diastasis.

7. Hot thermal agent modalities (e.g., drug-free heat wrap) are safe in the adult population

- in musculoskeletal disorders, especially in the following conditions:

o Evidence: groin pain, low back pain.

o Expertise: sub-acute/persistent muscle injuries, DOMS/DOMER, arthropathies (non-acute), osteoarthritis

8. Cryotherapy (e.g., ice or liquid nitrogen) is safe in the adult population

- in musculoskeletal disorders, especially in the following conditions:

o Evidence: arthroscopy, reconstruction of the anterior cruciate ligament, post-surgery.

o Expertise: Delayed Onset Muscle Soreness (DOMS)/Delayed Onset Muscle Soreness (DOMER), post-surgery, post-trauma (48h).

9. Therapeutic Ultrasound is safe in the adult population

- in musculoskeletal disorders, especially in the following conditions:

o Evidence: back pain, neck pain, carpal tunnel, rotator cuff disorder, lower limb soft-tissue disorder, knee osteoarthritis, fracture, acute fracture, ankle fracture, ankle and knee sprains,

o Expertise: hand and foot osteoarthritis, calcifications, enthesitis.

General notes and considerations related to subgroups:

Following a confirmed clinical prescription, applying the above PAMs is safe in the adult population (>18 years) under the supervision of an expert operator. For precautionary reasons, these statements are not extended to other subgroups of patients (e.g., children, adolescents, frail population, etc.) since insufficient literature is available.

Supplementary Files

Supplementary File 1. Ethical considerations

Participation in the Delphi survey is voluntary and by invitation. The questionnaire includes a beginning section to acquire consent and privacy for data processing. Participants are informed that the responses will have 'remained total confidentiality according to the Regulation on the protection of personal data' 679/2016 of the European Union, and that the results will be used for research purposes and a document shared at the corporate level [1]. The interested party may be interested in the rights provided for by art. 15, 16, 17, 18, 20, 21 and 22 of the Regulation mentioned above.

Database randomization and differential privacy access were achieved. In addition, "anonymization" by generalizing was performed.[2] The study project and data collection were managed and anonymously entrusted by the Unit of Clinical Epidemiology of IRCCS Istituto Ortopedico Galeazzi based in Milano. The data subject cannot be re-identified and is therefore outside the scope of the data protection law[3].

The row dataset was accessible to two researchers (SG, SB) excluded from participation in Delphi for the quantitative and qualitative analyses. This practice complies with the European standards for the use of aggregative data where the data subject cannot be re-identified, are not personal data and are therefore outside the scope of data protection law[3]. The final report only contains aggregate data. In the final document, we reported the names of the participants who have completed all rounds and gave their consent to disclose their names.

Supplementary File 2. Physical agent modalities description

1) Electrical stimulation: electrotherapeutic currents and waveforms to facilitate neuromuscular or sensory activity to improve muscle strength and reeducate muscle function.[4]

- Neuromuscular electrical stimulation (NMES): use of pulsed currents to stimulate motor nerves, which in turn produce tetanic contractions of the neuromuscular spindles, with or without joint movement.[5]

- Functional Electrical Stimulation (FES) uses electrical pulses to stimulate motor neurons or denervated muscle fibers directly to elicit a contraction during a functional activity (e.g., gait). FES is used in the treatment of orthopedic and neurological conditions.[6]

2) Neuromodulation, antalgic and interferential electrical currents :. electrotherapeutic currents and waveforms to influence physiological effects on the patient's body structures and functions aiming to modulate pain.[4]

- Transcutaneous electrical nerve stimulation (TENS): delivers electrical stimulation via electrodes placed over the intact skin surface near the source of pain to produce analgesia or hypoalgesia. A wide variety of pulsed waveforms are used, with frequencies typically in the range of 1-100Hz. The intensities are set to produce sensory stimulations alone or in combination with motor stimulations to produce muscle twitches (acupuncture-like TENS).[7]

- Transcutaneous Tibialis Posterior Stimulation (TTNS): a form of neuromodulation involving the use of electrical impulses to address urinary symptoms (e.g. overactive bladder) with inhibitory action on neurons of the spinothalamic tract (S2–S3).[8]

- Interferential current (IC): involves crossing two medium frequency currents (most commonly 4000 Hz), which reportedly generates a low-frequency 'beating' (amplitude-modulated) effect at between 0 and 150 Hz in the deep tissues.[9] These beat frequencies are believed to decrease pain, increase circulation and block nerve conduction.

3) **Extracorporeal shock wave therapy:** a nonsurgical treatment that uses the phenomenon of mechanotransduction (i.e., adapting cells biochemical activity, influencing cells migration, proliferation, differentiation and apoptosis) [10 11] to treat various musculoskeletal conditions (e.g., plantar fasciitis; tennis elbow). Shock wave therapy can be either extracorporeal or radial.[12]

- Extracorporeal shock wave therapy (ESWT) involves passing sound waves (or shock waves) through the skin to the affected area. Shock waves are single pulsed acoustic or sonic waves, which dissipate mechanical energy at the interface of two substances with different acoustic impedance. [13] They are produced by generators of an electrical energy source and require an electroacoustic conversion mechanism and a focusing

device. Three types of systems can be distinguished based upon the sound source: electrohydraulic, electromagnetic and piezoelectric systems. Various doses appear to be used, with no apparent consensus on the minimum therapeutic dose. As defined defined by Cacchio 2006 [14] as low-energy shock waves is less than 0.1 mJ/mm2 and high-energy shock waves: is 0.2 mJ/mm2 to 0.4 mJ/mm2).

- Radial shock wave therapy (RSWT) is generated through the acceleration of a projectile inside the handpiece of the treatment device and then transmitted radially from the tip of the applicator to the target zone. Radial shock waves show a lower peak pressure and a considerably longer rise time than extracorporeal shock waves. In RSWT, the focal point is not centred on a target zone, as occurs in focal ESWT, but on the tip of the applicator.[14]

4) **Laser therapy:** light source treatment, non-invasive, widely used to treat various musculoskeletal conditions.

- Low-level laser therapy (LLLT) generates a beam of light with a particular wavelength that can deliver light energy to tissue depths below the dermis [15]. Studies suggest that LLLT contributes to pain relief by reducing pro-inflammatory cytokines [16]. The effects of LLLT are considered to be dependent on dosage, wavelength, site and duration of treatment.[15 16]

- high level laser therapy (HLLT): laser with an output power greater than 500 mW or 0.5 Watts. HLLT creates heat on the surface of the skin due to their higher power density (irradiance).[17]

5) **Electromagnetic therapy:** based on Faraday's law of electromagnetic induction, to promote bone healing, treat osteoarthritis and inflammatory diseases of the musculoskeletal system, alleviate pain, enhance healing of ulcers and reduce spasticity[18].

- Pulsed Electromagnetic Field therapy (PEMF), which involves the delivery of pulsing (that is 'on-off') low-frequency magnetic fields through the body, which is believed to provide temporary pain relief by influencing tissue generation and cell proliferation.[19]

- Repetitive magnetic stimulation (rMS), which allows the transcutaneous induction of nerve stimulating electric currents. This technique requires extremely strong and sharp magnetic impulses (for example 15,000 amperes peak current; 2.5 T field strength; < 1 msec) applied by specially designed coils (< 10 cm) over the target area. Modern devices allow the repetition of up to 60 impulses per second. Mainly developed to study and influence brain functions, rMS also stimulates spinal chord fibres and peripheral nerves. Initial studies used peripheral rMS for therapeutic reasons, such as in myofascial pain syndrome[20]. Since the resulting small electric impulses are the nerve stimulating factor, rMS effects may be similar to TENS.

6) **Shortwave and microwave Diathermy**

- Tecartherapy or radiofrequency diathermy (RFD) is a non-invasive therapy and consists in the emission of high-frequency electromagnetic waves which increase tissue metabolism. This process promotes tissue repair and affects pain sensitivity.[21 22 23]

- Microwave diathermy: a deep heating modality that converts electromagnetic energy to thermal energy. Frequencies approved for therapeutic microwave are 915 MHz (wavelength 33 cm) and 2,456 MHz (wavelength 12 cm). The lower frequency has the advantage of increased depth of penetration but also the disadvantages of greater beam dispersion and the requirement of larger applicators. If muscle heating is primary objective, 915-MHz applicators are preferable to 2,456-MHz applicators. Average temperatures of approximately 41◦C at a depth of 1–3 cm have been demonstrated[24]

7) **Hot thermal agents:** heat transferred from an object with direct contact to the body. Heat therapy include hot packs, heatwraps, hot/warm water immersion, sauna. Heat treatment increases me-tabolism in tissues, promotes blood circulation and reduces pain. The temperature of the heat therapy is generally 35–40°C.[25 26]

8) **Cryotherapy:** cold is transferred from an object with direct contact to the body. Examples include cold packs, cold-water immersion (≤15°C), ice massage, the novel modality of cryotherapy. Cryotherapy is a treatment involving very short exposures to extremely cold dry air to the whole patient or a treatment area (mean temperature of the cryotherapy chamber is at −30°C, −80 to −110°C, or < −110°C). Cold treatment is thought to reduce swelling and cell metabolism, minimizing oedema, pain and injury.[25 27]

9) **Therapeutic Ultrasound:** delivers energy to deep tissue sites through ultrasonic waves (often at frequencies of 1 or 3 MHz and intensities between 0.1 watts/cm2 and 3 watts/cm2) using a crystal sound head. Treatment can be delivered in two forms, continuous (non- stop ultrasonic waves) and pulsed (intermittent ultrasonic waves[22 28]). The treatment aim to increase tissue temperature and induce non-thermal physiological changes (such as cell permeability and cell growth), which are believed to promote soft tissue healing and muscle relaxation.[29]

Supplementary File 3. Declaration of interest

Name and Surname	Affilitation	Scientific and Technical Societies	Conflict of interest declared
Armando Perrotta	IRCCS Neuromed, Pozzilli (IS)	Società Italiana per lo Studio delle Cefalee (SISC)	none
Viviana Rosati	A.U.O. Policlinico Umberto I	Società Italiana di Riabilitazione Neurologica (SIRN)	none
Enrico Marinelli	Department of Anatomical, Histological, Forensic, and Orthopedic Sciences, "Sapienza" University of Rome	Società Italiana di Medicina Legale e delle Assicurazioni (SIMLA) - Dipartimento di Scienze Biotecnologiche e Medico-chirurgiche Università di Roma Sapienza	none
Bianca Masturzo	Obstetrics and Gynecology department. Ospedale degli infermi. Ponderano (Biella)	Associazione degli Ostetrici e Ginecologi Ospedalieri Italiani (AOGOI)	none
Mauro Roselli	ASL CittadiTorino-Ospedale Martini-S.C. Ortopedia e Traumatologia	Ortopedici Traumatologi Ospedalieri d'Italia (OTODI)	none
Stefano Vercelli	Laboratorio di Ricerca in Riabilitazione 2rLab, Dipartimento Economia Aziendale, Sanità e Sociale. SUPSI. Manno (CH)	Federazione Italiana delle Associazione Scientifiche di Fisioterapia (FIASF)	none
Gianmarco Rea	Asl Latina, 04100 Latina, Italy	Società Italiana di Medicina Generale e delle Cure Primarie (SIMG)	none

Gianfranco Lamberti	Dipartimento Medicina Riabilitativa AUSL Piacenza	Società Italiana di Urodinamica (SIUD)	none
Roberto Bortolotti	UO Reumatologia Ospedale S.Chiara, Trento	Società Italiana di Reumatologia (SIR)	none
Chiara Torresetti	Paideia International Hospital	Associazione Italiana di Urologia Ginecologia e del Pavimento Pelvico (AIUG)	none
Fabio Bandini	Department of Neurology, ASL 3 Genovese, Genova, Italy	Società Italiana Neurologia (SIN)	none
Giuseppe Botta	Istituto Fisioterapico Michelangelo di Arezzo	Società Italiana di Flebolinfologia (SIFL)	none
Giancarlo Tancredi	Pediatric Department. Sapienza Università di Roma	Società Italiana di Pediatria (SIP)	none
Luigi Nappi	Department of Medical and Surgical Sciences Policlinico Riuniti di Foggia UNIVERSITY OF FOGGIA	Società Italiana Di Ginecologia E Ostetricia (SIGO)	none
Marco Scorcu	Servizio di Medicina dello Sport e dell'Esercizio Fisico, Cagliari, ATS	Federazione Medico Sportiva Italiana (FMSI)	none

	Sardegna, Cagliari, Italy		
Monica Pierattelli	Presidente SICuPP Toscana, Pediatra di libera scelta Campi Bisenzio (FI)	Societa' Italiana Delle Cure Primarie Pediatriche (SICuPP)	none
Carla Berliri	Cittadinanzattiva- APS - Sede Nazionale -Staff area Salute - Tribunale per i Diritti del Malato - Politiche della Salute-	Cittadinanzattiva - APS	none

Supplementary File 4. Panel of experts comments

ROUND	Electrical Stimulation	Neuromodulation, antalgic and interferential electrical currents	Extracorporeal shock wave therapy	Laser therapy	Electromagnetic therapy	Diathermy	Hot thermal agent modalities	Cryotherapy	Ultrasound
Round 1	My Likert Scale rating of 9 stems not only from the numerous evidence but also from the results of my clinical experience. In cases of perineal hypotonia and sphincter deficits, electrical stimulation has facilitated recovery times by enhancing manual work and proprioception during the learning phase.	The primary application of TTNS in my practice, aside from addressing bladder disorders (overactivity), is in the management of painful syndromes, such as spasms of peri-urethral muscles in patients with recurrent post-coital cystitis, vulvodynia, and pudendal neuralgia.	In this case, my assessment requires specificity: In many instances, women experiencing resistant pelvic pain may not readily accept the use of shock waves, as it is an impactful therapy that can cause initial discomfort. Among various instrumental approaches for this patient group, it would not be my first choice. On the other hand, my perspective on shock waves for the treatment of male pelvic pain or erectile dysfunction is quite different; in this case, I positively endorse the statement.	completely agree.	I cannot provide a judgment as I lack the appropriate training and experience in its use.	Thanks to the use of diathermy, I can achieve excellent results in the treatment of dermatological conditions affecting the genital mucosa, such as Lichen Sclerosus. In pelvic pain, patients appreciate the mild heat generated by the diathermy probe, allowing for more effective therapy in the area. Currently, this treatment is consistently integrated into all treatment plans, irrespective of individual clinical situations, without causing discomfort or triggering sensitivity reactions	Limited experience in menstrual pain for just the efficacy. However it is related to other type of hot termal agents (e.g, infrared therapy)	Agreed, but the patient must be adequately instructed in advance on the use and timing of cryotherapy, for example, ice packs postpartum or in inflammatory hemorrhoidal syndromes. Discourage self ice application, and encourage the use of devices designed for healthcare purposes. It is a very useful and easily administered therapy but potentially 'dangerous' if mishandled at home, for instance, the risk of cold burns	For my expertise US is safe in pelvic disorders.
	In the absence of expertise in the pelvic-perineal and neurological domains, the opinion is limited to the musculoskeletal field	In the absence of expertise in the pelvic-perineal and neurological domains, the opinion is limited to the musculoskeletal context only.	Shock waves are not recommended in individuals during the developmental age since their tissues and cartilage are still in the developmental phase	In the absence of expertise in pelvic-perineal, lymphatic, and neurological domains, the opinion is limited to the musculoskeletal context only	In the absence of expertise in pelvic-perineal areas, the opinion is confined to the musculoskeletal context only. The indicated median score pertains to uncertainty regarding the safety of persistent use (long term), as I am not aware of literature data on adverse events for such durations. For treatment cycles falling within the time frames investigated in the	In the absence of expertise in the pelvic-perineal domain, the opinion is confined to the musculoskeletal context only. The moderate agreement with the safety statement primarily concerns uncertainties regarding the operator's safety with high daily exposure to the equipment, especially if potential risk factors are present (e.g., pregnancy or	In my experience, I have observed several cases of mild and transient skin irritations.	It is the only treatment I have seen used in younger age groups	For my expertise US is safe in pelvic disorders.

					available RCTs, the judgment is certain	the presence of oncological pathologies, even if unrecognized). I am not aware of studies monitoring the health of operators exposed to moderate or high levels of possible electromagnetic fields generated by the equipment. Regarding the equipment's safety for the patient, the judgment of agreement is certain.			
	NMES is widely used to address certain types of pharyngeal dysfunction in adults with dysphagia, but there is limited evidence demonstrating its effectiveness or appropriateness for pediatric patients. Reference: Andreoli S et al. Int J Pediatr Otorhinolaryngol 2019;127:109646. doi: 10.1016/j.ijporl.2019.109646.	NA in some pelvi-perineal and neurological disorders	NA in some pelvi-perineal and neurological disorders	Adulthood or in individuals with skeletal maturity	PEMF therapy is not recommended for children who have not yet completed their growth phases	It is not recommended for children as their biological tissues are still in the growth phase	I suggest emphasizing more strongly that the use is specifically intended for non-acute arthropathies	Risk of cold burn	Rarely used in adolescents after sports-related traumas
	NA in some perineal neurological disorders	For my experience mainly for neurological disorders		NA in some neurological and perineal disorders	NA for some perineal disorders	NA for some perineal disorders	for my expertise, uncertain in groin pain		
	For my expetise mainly in migraine			LLLT expertise in some neurological conditions (e.g, migraine)	for my expertise mainly used in migraine				
Round 2	Litemited in some neurological setting	Useful also for vulvodynia, rectal spasms with anal pain	Uncertainity in some neurological disorders	limited evidence in some neurological disorders		I additionally include post-genital ulcer treatment, hypertonicity, and genital swelling in patients with pelvic pain	Limited experience in menstrual pain for just the efficacy. However it is related to other type of hot termal agents (e.g, infrared therapy)	Cryotherapy in pelvic floor rehabilitation is used for the treatment of pain from hemorrhoidal inflammation, postpartum contusion, postpartum hypotonia with pronounced laxity, and for some patients, it	For my expertise US is safe in pelvic disorders.

								is beneficial in addressing the sensation of genital swelling in chronic pelvic pain	
				I do not have the right clinical experience to rate it with confidence. In my clinical practice, patients who have undergone LLLT have shown a greater tendency towards increased genital dryness. Therefore, the treatment requires additional measures such as enhanced hydration, for example, through the use of serums/ointments/ suppositories during the treatment period, to mitigate certain side effects that may cause discomfort to the patients.					

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