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Complete List of Authors:	Gianola, Silvia; IRCCS Galeazzi Orthopaedic Institute, Unit of Clinical Epidemiology Bargeri, Silvia; IRCCS Galeazzi Orthopaedic Institute, Unit of Clinical Epidemiology Pellicciari, Leonardo; IRCCS Istituto Delle Scienze Neurologiche di Bologna Gambazza, Simone; Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico Rossettini, Giacomo; Università degli Studi di Verona, School of Physiotherapy Fulvio, Anna; Associazione Italiana di Fisioterapia Genovese, Vincenzo; Associazione Italiana di Fisioterapia Benedini, Matteo; Associazione Italiana di Fisioterapia Proverbio, Emanuele; Associazione Italiana di Fisioterapia Cecchetto, Simone; Associazione Italiana di Fisioterapia; Provincia autonoma di Trento Azienda Provinciale per i Servizi Sanitari Castellini, Greta; IRCCS Istituto Ortopedico Galeazzi, Clinical Epidemiology Unit Turolla, Andrea; Alma Mater Studiorum University of Bologna; IRCCS Policlinico Sant'Orsola-Malpighi
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Evidence-informed and consensus-based indications about SAFEty of Physical Agent Modalities Practice in physiotherapy and rehabilitation medicine (SAFE PAMP): a national Delphi of healthcare scientific societies

Authors List

Silvia Gianola[1], Silvia Bargeri[^1], Leonardo Pellicciari[2], Simone Gambazza[3], Giacomo Rossettini[4], Anna Fulvio[5], Vincenzo Genovese[5], Matteo Benedini[5], Emanuele Proverbio[5], Simone Cecchetto[5,6], Greta Castellini[1], Andrea Turolla[7,8*] and SAFE PAMP Collaborators*

1. IRCCS Istituto Ortopedico Galeazzi, Unit of Clinical Epidemiology, Milan, Italy
2. IRCCS Istituto delle Scienze Neurologiche di Bologna, Bologna, Italy
3. Healthcare Professions Department, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy
4. School of Physiotherapy, University of Verona, Verona, Italy
5. Associazione Italiana di Fisioterapia (AIFI), Rome, Italy
6. Direction of Health Professions, APSS, 38014 Trento, Italy.
7. Department of Biomedical and Neuromotor Sciences-DIBINEM, Alma Mater Studiorum Università di Bologna, 40138 Bologna, Italy.
8. Division of Occupational Medicine, IRCCS Policlinico Sant'Orsola-Malpighi, 40138 Bologna, Italy.

^corresponding author

*co-last

SAFE PAMP Collaborators

Chiara Torresetti, on behalf of AIUG (Associazione Italiana di Urologia Ginecologia e del Pavimento Pelvico)

Bianca Masturzo, on behalf of AOGOI (Associazione Ostetrici Ginecologi Ospedalieri Italiani)

Carla Berliri, on behalf of Cittadinanzattiva Associazione di Promozione Socialez

Mauro Roselli, on behalf of OTODI (Ortopedici e Traumatologi Ospedalieri D'Italia)

Stefano Vercelli, on behalf of FIASF (Federazione Italiana delle Associazioni Scientifiche di Fisioterapia)

Marco Scorcu, on behalf of FMSI (Federazione Medico Sportiva Italiana)

Giuseppe Botta, on behalf of SIFL (Società Italiana di Flebolinfologia)

Luigi Nappi, on behalf of SIGO (Società Italiana Di Ginecologia E Ostetricia)

Gianmarco Rea, on behalf of SIMG (Società Italiana di Medicina Generale e delle cure primarie)

Enrico Marinelli, on behalf of SIMLA (Società Italiana di Medicina Legale e delle Assicurazioni)

Fabio Bandini, on behalf of SIN (Società Italiana di Neurologia)

Roberto Bortolotti, on behalf of SIR (Società italiana di Reumatologia)

Viviana Rosati, on behalf of SIRN (Società Italiana di Riabilitazione Neurologica)

Armando Perrotta, on behalf of SISC (Società Italiana per lo Studio delle Cefalee)

Gianfranco Lamberti, on behalf of SIUD (Società Italiana di Urodinamica)

Monica Pierattelli, on behalf of SICuPP (Societa' Italiana Delle Cure Primarie Pediatriche)

Giancarlo Tancredi, on behalf of SIP (Società Italiana di Pediatria).

ABSTRACT: 264 words

Objective: A shared consensus on safety about Physical Agent Modalities (PAMs) in physiotherapy and rehabilitation is lacking. We aimed to develop evidence-informed and consensus-based indications about 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 - AIFI) to identify areas and questions for developing indications about the safety of most common used PAMs in physiotherapy and rehabilitation. We invited 28 National Scientific and Technical Societies (STS) as a multidisciplinary and multi-professional panel of experts to evaluate the proposed indications and formulate additional inputs. The level of agreement was measured with a 9-points Likert scale. Consensus in the Delphi rounds was assessed using the rating proportion with a threshold of 75%.

Results: Seventeen (61%) out of 28 STS participated involving their most representative expert member. Experts composing the panel were mainly clinicians (88%) reporting multiple 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 indications about the safety of PAMs in adults (electrical stimulation neuromodulation, extracorporeal shock wave therapy, laser therapy, electromagnetic therapy, diathermy, hot thermal agents, cryotherapy and therapeutic ultrasound) with a general note about populations subgroups.

Conclusions: The resulting evidence-based indications inform patients, healthcare providers and policy-makers regarding the safe application of PAMs in physiotherapy and rehabilitation. Future research is needed to extend this consensus on pediatric, adolescent and frails patients.

Key Words: Physical Therapy Modalities, Safety, Rehabilitation, Physical and Rehabilitation Medicine, Delphi Technique

STRENGHT AND LIMITATIONS

- Indications developed about safety of Physical Agents Modalities in rehabilitation have a solid scientific background coming from 117 systematic reviews
- Indications were discussed and approved by a multidisciplinary and multiprofessional panel of experts including clinicians, researchers, healthcare managers, forensic, patients and lay members
- The main limitation is that indications were not extended to specific subgroups of patients (e.g., children, adolescents, frails, etc.) since insufficient literature is available.

INTRODUCTION

Physical agent modalities (PAMs) such as electrical stimulation, extracorporeal shock wave therapy, laser therapy, hot/cold thermal agents are widely used in adjunction to other physiotherapy and rehabilitation treatments to produce therapeutic responses in tissues (e.g., reducing pain and swelling) [1-4]. Among different interventions, they are prescribed and applied by healthcare professionals in various medical specialties (e.g., neurology, orthopedics, geriatrics, pediatrics, oncology, urogynecology) to carry on patient-centered healthcare pathways. However, both clinicians and patients should be informed about their safety with regard to patient-centered care pathways[5]. A Canadian guideline on contraindications and precautions in the use of the six most common physical agents (i.e., ultrasound, cryotherapy, superficial thermal agents, electrical stimulation, low-level laser therapy, and short-wave diathermy) was published in 2010; for example, deep vein thrombosis or thrombophlebitis and haemorrhagic conditions, pacemaker or other implanted electronic device, were reported as contraindications for all the six physical agents.[6].

Moreover, the safety of PAMs in patients undergoing physical therapy and rehabilitation was recently assessed by a recent scoping review investigating the occurrence of adverse events after the application of these therapies[7, 8]: nine PAMs (i.e., cryotherapy, electrical stimulation, transcutaneous electrical nerve stimulation, functional electrical stimulation, extracorporeal shockwave therapy, laser therapy, magnetotherapy, pulsed electromagnetic field and diathermy) and no important harms about these interventions were found, except for extracorporeal shockwave therapy reporting mild adverse events.

However, an up-to-date multidisciplinary and multiprofessional expert consensus on PAMs safety is still lacking. Therefore, the purpose of SAFE PAMP (SAFEty of Physical Agent Modalities Practice) consensus in physiotherapy and rehabilitation is to develop evidence-informed and consensus-based indications[9] on safety of PAMs, by consensus via a RAND Delphi procedure among content experts.

METHODS

Design

A RAND-modified Delphi rounds' survey process was used as the facilitation technique for reaching consensus[10].We followed the guidance on "Conducting and REporting of DElphi Studies" (CREDES) that can be generalized for our field[11], according with the EQUATOR initiative [9].

This project is exempted from ethical approval according to the "ethics and data protection" regulations of the European Commission[12]. More details are reported in **Supplementary File 1**. The protocol was a-priori registered on OSF online repository (https://osf.io/53j27).

The process consisted of three phases: (i) establishment of the steering committee and invitation of experts from scientific and technical societies (STS) to constitute the panel; (ii) generation of indications by the steering committee using a comprehensive approach based on a published scoping review of existing systematic reviews on PAMs safety in physiotherapy and rehabilitation medicine[7, 8] and on expertise from content expert consultations; (iii) voting of indications through a national Delphi survey from the panel of experts aiming to identify, assess and modify indications importance for each field (e.g., musculoskeletal); (iv) as last round, an online workshop meeting was attended by participants to finalize the list of indications reaching the final consensus (**Figure 1**). Finally, we planned a dissemination of the final indications list as good clinical practices.

[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 that was responsible for: the definition of the list of indications, the selection of STS for expert participants, the development of the Delphi questionnaires, the analysis of responses and handling of feedback from participants, after each round.

The steering committee involved 11 content experts and members of the Italian Association of Physiotherapy (Associazione Italiana di Fisioterapia – AIFI). In order to assure the external validity of the consensus process, the group included two content experts on PAMs (MB, EP), three on rehabilitation of musculoskeletal disorders (GR, VG, SB), one on neurological physiotherapy and neuroscience (AT), one on pelvic floor rehabilitation (AF), and four methodologists (SGa, SGi, GC, LP).

Panel of experts

It is known that the impact of the quality of the final recommendations is given by the diversity of a Delphi panel whereas no agreement on the panel size for Delphi studies exist. Panels of 20–30 participants are common.[13, 14] Thus, the steering committee invited 28 multidisciplinary and multiprofessional STS dealing with physiotherapy and rehabilitation care. These STS are entitled to generate good clinical practice guidelines by the published list of the Italian Ministry of Health [15, 16]. The panel of expert members was multidisciplinary and multiprofessional including clinicians, researchers, and healthcare managers coming from different fields[14] (e.g, orthopedics, neurology). The panel included also forensic, patients and lay members (e.g., people working with relevant voluntary organizations). Each STS delegated the most representative member involved in physiotherapy and rehabilitation care to join the panel of experts.

Phase II. **Generation of indications**

The steering committee formulated indications ensuring that all the potentially relevant topics in the field would be included in the initial list of questions, for the first Delphi round.

Indications to be included in the questionnaires were selected based on the literature[7, 8] and clinical expertise. We moved from a recent scoping review including 117 systematic reviews on the safety of PAMs in physiotherapy and rehabilitation medicine[7, 8]. This type of review is a method for knowledge synthesis used to map the concepts underpinning a research area and the main sources and type of

evidence available. Clinical expertise was assured by content experts of AIFI in musculoskeletal disorders, neurological physiotherapy and pelvic floor rehabilitation. They discussed indications through brainstorming on the following research area:

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

Supplementary File 2 reported details about each included intervention.

Phase III. Voting of indications through Delphi Rounds

We used an electronic Delphi process allowing participants to submit responses anonymously and independently without being biased by other participants' identities and responses. The steering committee sent a blinded electronic voting platform (by a web-based survey) to the panel of experts using the SurveyMonkey online platform (Palo Alto, CA, USA; www.surveymonkey.com).

The web-based survey consisted of two sections: the first regarded the participants' demographics (e.g., type of profession, the field of expertise, years of experience), and the second covered how to vote for indications. Particularly, the panel of experts evaluated the proposed indications and formulated additional comments using a free text box to ensure complete coverage of the topic. According to the RAND method, for each indication, the panel of experts used a 9-points Likert scale

(i.e., 1-3 = highly inappropriate, 4-6 = undecided, 7-9 = highly appropriate) for rating the level of concordance.

In addition, the experts can abstain from voting, selecting the answer "Not my expertise" for indications when they felt not have the appropriate level of expertise to rate.

A summary of results was provided according to the total number of experts voting as feedback to inform panel members on consensus development with feedback and descriptive statistics incorporated for the next round. Panel of experts were asked to re-rate their evaluation in more rounds only for those indications needing clarification, or for indications for which consensus (i.e., ≥ 75% in 7-9 points scale or in 1-3 points scale) was not reached.

Anonymous report of each round was provided to each expert showing the distribution of responses for each indication with all additional comments provided in the free text box. Based on previous voting, indications were modified and presented for the next round. Up to three remind emails for completion were sent to each component individually. Data collection occurred over a 5-month period (June-November 2022).

Phase IV. Workshop Meeting as last round

After reaching a consensus, the steering committee joined an online meeting as the last round to refine indications according to each expert contribution and to confirm indications to be included in the final criteria list. Finally, the panel of experts was asked to vote on the final indications list for the closing audit procedure.

Definition and calculation of consensus

In agreement with the RAND appropriateness method, to inform the development of consensus we adopted predefined criteria[17] assessing the consensus in the Delphi method using the proportion of ratings with a threshold of 75% according to previous review [18]. Particularly:

1. Consensus in: ≥ 75% of participants scored the item as "critical" (score 7 to 9) and < 15% scored the item as of "limited importance" (score 1 to 3)
2. Consensus out: ≥ 75% of participants scored the item as of "limited importance" (score 1 to 3) and < 15% scored the item as "critical" (score 7 to 9)
3. No consensus: All other results.

Statistical Analysis

We used descriptive statistics such as mean and standard deviation (SD), median and interquartile range (IQR) or absolute value and frequency as appropriate to summarize general characteristics of participants and percentage of agreement during the Delphi rounds.

Role of the Funding Source

The work was supported by AIFI. The funder played no role in the design, conduct, or reporting of this study.

Patient and public involvement

One patient representative was involved as expert panellist in this study to rate the indications.

RESULTS

Participants

Overall, 17 out of 28 (61%) invited STS responded to the questionnaire. The Delphi process flow chart with the STS participants list is reported in **Figure 2**. One expert represented each STS. Most experts were clinicians (88%), with half having expertise in the musculoskeletal field (47%). Experts had a median experience of 30 years (IQR:17-36) in their area of expertise. The general characteristics of the experts included in this study are reported in **Table 1.** No conflict of interest was present (**Appendix 1**).

[Figure 2]

[Table 1]

Delphi rounds

Two rounds Delphi were necessary to reach consensus.

Round 1

Overall, 17 experts representing each of the invited STS completed the survey. All indications passed the first round with a consensus out of 75% (**Table 2**). Five experts provided justifications for their choices (e.g., examples of clinical practice) and gave important inputs for some indications. In particular, additional comments regarded concerns about the definition of children and adolescent age, the safety of patients or providers and acceptability. Thus, round 2, was prepared adding specific notes based on suggestions posed: the age to define children and adolescents and the focus on the safety of patients.

[Table 2]

Round 2

Overall, 14 STS (82%) completed the whole survey. All the indications passed the first round with a consensus out of 75%. (**Table 2**). One expert of the panel provided additional comments reporting examples from clinical practice.

Workshop Meeting as last round

On September 27, 2022 nine STS (53%) joined the online meeting to discuss comments, justifications and highlights. A comprehensive digital presentation of Round 1 and Round 2 findings were reported during the workshop. Indications were finally reworded, as suggested by the participants. In addition, the panel of experts suggested introducing a general note considering different subgroups of the population (e.g., children, adolescents, frails). A final list of indications with a general note was shared in order to reach the final approval through a last round. All STS (100%) approved and released the final indications list of indications. One expert voted the option "Not my expertise" in the indication on the cryotherapy (**Table 2**). In **Appendix 2,** the whole document released for good clinical practice with details of sources (evidence and expertise) and application in different population settings was reported.

DISCUSSION

This study aimed to develop indications about the safety of PAMs in physical therapy and rehabilitation medicine. These indications were developed by a steering committee (including clinical and methodological experts) of AIFI and informed by 17 national STS with high expertise in different fields related to physiotherapy and rehabilitation (e.g., orthopedics, neurology), including forensic scientists, patients and lay members (e.g., people working with relevant voluntary organizations).

The response rate was moderate with 61% of participation, as suggested by literature[19]. All nine indications were approved in the first round, reaching an important consensus of over 75%, with minor edits on age and fields of applications refined with a second round. After a workshop meeting, a general note was added limiting the use of PAMs to the adult population (>18 years) and all panel experts approved and released the final indications list with overall consensus. In summary, all PAMs proposed are safe to the adult population (>18 years) and can be prescribed and applied by a healthcare provider (e.g., physiotherapist, physician) formed and informed as a requirement from education and licensure[20]. Before proposing PAMs to patients, clinicians have to keep in mind the individual medical history (e.g., comorbidities) during the comprehensive initial examination to better

determine the diagnosis, prognosis, anticipated goals and expected outcomes for identified impairments, activity limitations and participation restrictions[21]. Thus, following an evidence-based approach, healthcare providers should propose the various efficacious treatment options available according to patients' needs and preferences. In this context, patient should be informed of the potential undesirable effects, especially for the application of PAMs. In particular, in case of ESWT as some expected mild adverse events (e.g., pain, erythema) at the application site can occur [7].

For safety purposes, developed indications were not generally extended to other subgroups such as children, adolescents and frail people, since limited and insufficient literature on harms is available.[22] For example, in children and adolescents some PAMs could influence the biological tissues still in the growth phase [23 6, 24]. This population have open growth plates and their ligaments (tissues holding bone to bone) are stronger than the bony attachment sites, where they serve as connectors.

Thus, adopting safety principle, decision-makers adopt precautionary measures when scientific evidence on harms is uncertain, and the population is vulnerable[25 26, 27] (e.g., populations historically considered at risk for being misused in clinical research or for whom a truly voluntary decision may be compromised from a regulatory perspective such as children or frail people).

Considering an evidence-based approach, clinicians should balance efficacy and safety, according to patients' preferences. Among all the rehabilitation interventions with demonstrated efficacy[28, 29], those with trivial adverse events should be encouraged (after informing the patient of the possible occurrence of mild adverse events), whereas those with unknown related harms should not. "*Primum non nŏcēre*" is one of the essential ethical principles of medicine; first of all a treatment should not cause harms to the patient[30].

Implications for clinical practice

Good practices for safety of patients should be managed by national agencies with a living monitoring system and shared in international initiatives such as the WHO Global Patient Safety Challenge

Medication Safety[31] to facilitate the strengthening of systems and practices adopting corrective action within countries.

In this context, our consensus could take place into the Good Clinical Practices (GCP) of the Italian Ministry of Health system by Istituto Superiore di Sanità (ISS)[32] for the production of national guidelines and the National Agency for Regional Health Services (Agenzia Nazionale per i Servizi Sanitari Regionali – AGENAS)[33] for reporting any experience of improvement in patient safety made by healthcare organizations.

Together with public or private healthcare institutions and organizations and in accordance with recent national legislation on clinical responsibility and safety of treatment[16], STS must sustain any initiative on safety of interventions, with the largest involvement of stakeholders included patients at first instance. The STS should act as facilitator of dissemination of GCP in different strategies. On one hand STS can promote local experiences of improvement in patient safety stored in shared repository (i.e., AGENAS)[33] on the light of evidence-based consensus (e.g., SAFE PAMP) to facilitate national collaboration between different institutions. On the other hand, STS can disseminate a plain patient-oriented version of good clinical practices indications. We planned to develop patient and stakeholder versions of our evidence-informed and consensus-based indications. We aim to use a conceptual framework based on public health digitalization to put people and patients at the center of care delivery, supporting patient empowerment and making healthcare system more efficient and safer. [34, 35] For example, we can plan stakeholders meetings and webinars, as well as educations and counselling via pamphlets/video/and social messages.

Implications for research

We believe that indications developed by the multidisciplinary and multi-professionally panel of experts can be generalized worldwide. These results could provide essential information for Good Clinical Practices for the production of national and international guidelines to improve patient safety and decrease avoidable harms related to interventions. However, in some rehabilitation fields,

indications about safety were offered only on clinical expertise in the absence of evidence. The absence of evidence is not evidence of absence [36]. Studies should convey their efforts to plan and adequately report adverse events before objectively estimating these harms. The assessment, monitoring and reporting of adverse events should be mandatory in protocols of primary studies, in prospective registration and in public access. This can allow to study data, fulfilling ethical obligations towards patients, and ensuring a basis for fully-informed decision making in the healthcare system. We call for multicentric randomized controlled trials based on the core outcome set also for harms and not only for benefit[37].

As well, specific subgroups of populations should be studied. It is a serious matter to exclude a group from research eligibility, and this must be done only when no less restrictive option is sufficient to ensure protection from undue risk. Deciding to exclude certain groups from studies to protect them from the risks inherent in clinical research, investigators take away patients' right to decide the desirable participation in research.[38]

In addition, future studies can better explode our indications to ensure the optimal modality application of the proposed PAMs (e.g., optimal voltage, amperage, frequency, current density, dose) especially for the subgroups mentioned above where therapies should be proposed according to population-specific characteristics (e,g., age of children).[39]

Limitations

This is the first effort to develop indications 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 (https://osf.io/w8kgs) the consensus criterion used to determine agreement within the Delphi process [17, 40].

Indications from this study have a solid scientific background and external validity since they were developed according to a previous evidence based scoping review[7, 8] (protocol stored at https://osf.io/6vx5a/) and discussed by large groups of experts with various backgrounds, including

lay member and patients. The panel of experts, as occurs in clinical practice guidelines, declared their interests to inspect any possible related conflict of interest.

Some limitations should be acknowledged. We used a consensus threshold of 75% even if the definition varies widely in the literature and it is poorly reported.[18] However, our threshold was one of the most conservative and in all rounds the consensus was reached with high percentage of agreements.

In addition, even if PAMs were found to be safe in this consensus, we did not exclude that some patients could experience mild adverse events (e.g., bruising, muscle soreness) that can be underestimated considering the real-world data (RWD) relating to patient health status. Patients experiences of adverse events should be collected in public dataset of RWD from electronic health records and insurance claims[41]. However, the analysis of RWD requires special vigilance to prevent data users from drawing unjustified conclusions not supported by data, based on spurious correlations [41]. Some initiatives across countries exists such as the Food and Drug Administration (FDA) repository for the reporting of adverse events related to FDA-approved devices[42] and the European database on medical devices (EUDAMED) to access information for the public and healthcare professionals[43].

Accelerating and standardize national and international medical device regulation can promote an efficient and effective regulatory model for medical devices responsive to emerging challenges while protecting and maximizing public health and safety[44]

CONCLUSION

These evidence-based indications inform patients, healthcare providers and policy-makers regarding the safety of a wide rage PAMs used in physiotherapy and rehabilitation after a comprehensive clinical evaluation of patients' needs. This consensus can provide a basis for decision-making and future research on this field.

DECLARATIONS

Author Contributions

Concept/idea/research design: S. Gianola, S. Bargeri, G. Castellini

Writing: S. Gianola, S. Bargeri, G. Castellini

Data collection: S. Gianola, S. Bargeri

Data analysis: S. Gianola, S. Bargeri

Project management: S. Gianola, S. Bargeri

Consultation (including review of manuscript before submitting): S. Gianola, S. Bargeri, L. Pellicciari, S. Gambazza, G. Rossettini, A. Fulvio, V. Genovese, M. Benedini, E. Proverbio, S. Cecchetto, G. Castellini, A. Turolla, and SAFE PAMP Collaborators

Ethics Approval

This study was declared exempt from institutional review board review

Disclosures

The authors declared they had no conflicts of interest.

Funding

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Data sharing statement

Research data are stored in OSF repository https://osf.io/w8kgs/

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Figure 1. Phases of the RAND Delphi process

Figure 2. Flow chart of Delphi process

Table 1. General characteristics of experts

Table 2. Agreement results for each round

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Tables

Table 1. General characteristics of experts

Professional profile*	Responses (N=17)
Clinicians	88.0%
Researchers	41.0%
Management	23.5%
Field of expertise*	
Musculoskeletal	47.0%
Pelvic floor disorders	23.5%
Neurological	18.0%
Lymphatic disorders	6.0%
Other**	35.3%

*more than one answer was possible

** e.g, lay or forensic members

Table 2. Agreement results for each round

Indications about 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 pointson 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

Abbreviations: NME: not my expertise

Appendix 1. SAFE PAMP Collaborators

Name and Surname	Affilitation	STS	COI
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	Federazione Medico Sportiva Italiana (FMSI)	none

	dell'Esercizio Fisico, Cagliari, ATS 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

Legend: COI, Conflict of Interest; STS, Scientific and Technical Societies

Appendix 2. Final criteria list

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, faecal 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, faecal 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 disease.

Patients should be informed of the potential undesirable effects after applying ESWT. Indeed, a recent literature review showed some expected mild adverse events, such as pain and erythema, at the application site [7].

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 oedema, algodystrophy, arthrosis.

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

o Evidence: persistent pelvic pain and urinary incontinence.

o Expertise: faecal 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 heatwrap) 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,

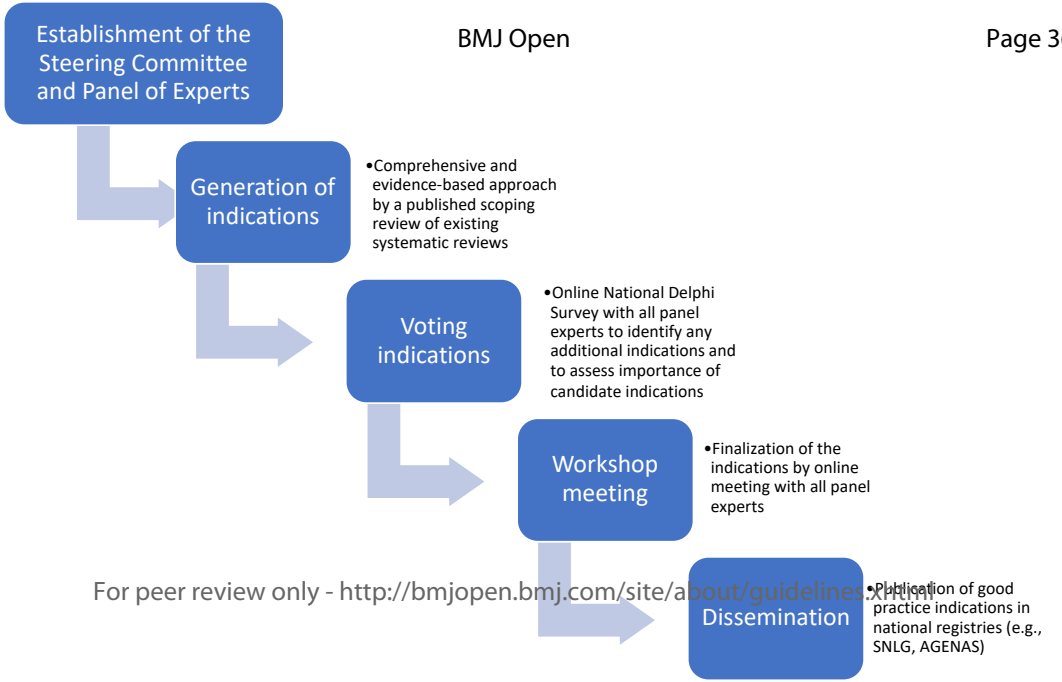
  - o Expertise: hand and foot osteoarthritis, calcifications, enthesitis.

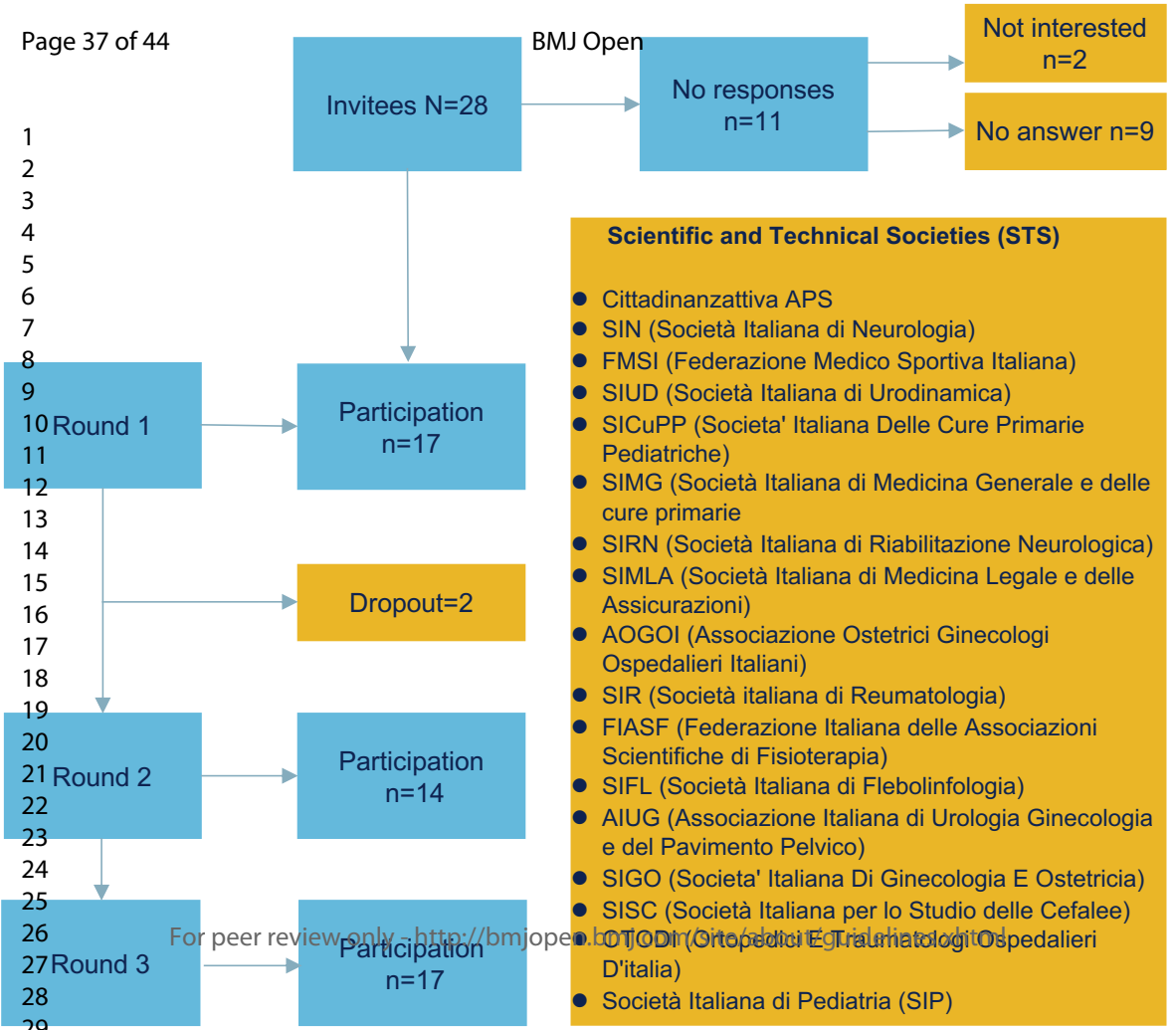
General note and considerations related to subgroups:

Following a confirmed clinical prescription, the applications of the above physical therapies are safe in the adult population (>18 years) under the supervision of an expert operator. For precautionary

652 reasons, these indications are not extended to other subgroups of patients (e.g., children,

653 adolescents, frails, 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]

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CREDES Checklist:

Recommendations for the Conducting and REporting of DElphi Studies (CREDES)[1]

Technology in Palliative Care (TIP): the identification of digital priorities for palliative care research using a modified Delphi method

Items of reporting	Reported on page
Purpose and rationale. The purpose of the study should be clearly defined and demonstrate the appropriateness of the use of the Delphi technique as a method to achieve the research aim. A rationale for the choice of the Delphi technique as the most suitable method needs to be provided.	5 - 6
Expert panel. Criteria for the selection of experts and transparent information on recruitment of the expert panel, sociodemographic details including information on expertise regarding the topic in question, (non)response and response rates over the ongoing iterations should be reported.	7
Description of the methods. The methods employed need to be comprehensible; this includes information on preparatory steps (How was available evidence on the topic in question synthesised?), piloting of material and survey instruments, design of the survey instrument(s), the number and design of survey rounds, methods of data analysis, processing and synthesis of experts' responses to inform the subsequent survey round and methodological decisions taken by the research team throughout the process.	7-10
Procedure. Flow chart to illustrate the stages of the Delphi process, including a preparatory phase, the actual 'Delphi rounds', interim steps of data processing and analysis, and concluding steps.	6-9; Figure 1-2
Definition and attainment of consensus. It needs to be comprehensible to the reader how consensus was achieved throughout the process, including strategies to deal with non-consensus.	9-10
Results. Reporting of results for each round separately is highly advisable in order to make the evolving of consensus over the rounds transparent. This includes figures showing the average group response, changes between rounds, as well as any modifications of the survey instrument such as deletion, addition or modification of survey items based on previous rounds.	10-12; Table 2; Appendix 2
Discussion of limitations. Reporting should include a critical reflection of potential limitations and their impact of the resulting guidance.	15-16
Adequacy of conclusions. The conclusions should adequately reflect the outcomes of the Delphi study with a view to the scope and applicability of the resulting practice guidance.	16
Publication and dissemination. The resulting guidance on good practice in palliative care should be clearly identifiable from the publication, including recommendations for transfer into practice and implementation. If the publication does not allow for a detailed presentation of either the resulting practice guidance or the methodological features of the applied Delphi technique, or both, reference to a more detailed presentation elsewhere should be made (e.g. availability of the full guideline from the authors or online; publication of a separate paper reporting on methodological details and particularities of the process (e.g. persistent disagreement and controversy on certain issues)). A dissemination plan should include endorsement of the guidance by professional associations and health care authorities to facilitate implementation.	13-14

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

Authors List

Silvia Gianola[1], Silvia Bargeri[1], Leonardo Pellicciari[2], Simone Gambazza[3], Giacomo Rossettini[4], Anna Fulvio[5], Vincenzo Genovese[5], Matteo Benedini[5], Emanuele Proverbio[5], Simone Cecchetto[5,6], Greta Castellini[1], Andrea Turolla[7,8*] and SAFE PAMP Collaborators*

1. IRCCS Istituto Ortopedico Galeazzi, Unit of Clinical Epidemiology, Milan, Italy
2. IRCCS Istituto delle Scienze Neurologiche di Bologna, Bologna, Italy
3. Healthcare Professions Department, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy
4. School of Physiotherapy, University of Verona, Verona, Italy
5. Associazione Italiana di Fisioterapia (AIFI), Rome, Italy
6. Direction of Health Professions, APSS, 38014 Trento, Italy.
7. Department of Biomedical and Neuromotor Sciences-DIBINEM, Alma Mater Studiorum Università di Bologna, 40138 Bologna, Italy.
8. Unit of Occupational Medicine, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy

Corresponding author:

Silvia Bargeri

IRCCS Istituto Ortopedico Galeazzi, Unit of Clinical Epidemiology, Milan, Italy

silvia.bargeri@grupposandonato.it

*co-last

SAFE PAMP Collaborators

Chiara Torresetti, on behalf of AIUG (Associazione Italiana di Urologia Ginecologia e del Pavimento Pelvico)

Bianca Masturzo, on behalf of AOGOI (Associazione Ostetrici Ginecologi Ospedalieri Italiani)

Carla Berliri, on behalf of Cittadinanzattiva Associazione di Promozione Socialez

Mauro Roselli, on behalf of OTODI (Ortopedici e Traumatologi Ospedalieri D'Italia)

Stefano Vercelli, on behalf of FIASF (Federazione Italiana delle Associazioni Scientifiche di Fisioterapia)

Marco Scorcu, on behalf of FMSI (Federazione Medico Sportiva Italiana)

Giuseppe Botta, on behalf of SIFL (Società Italiana di Flebolinfologia)

Luigi Nappi, on behalf of SIGO (Società Italiana Di Ginecologia E Ostetricia)

Gianmarco Rea, on behalf of SIMG (Società Italiana di Medicina Generale e delle cure primarie)

Enrico Marinelli, on behalf of SIMLA (Società Italiana di Medicina Legale e delle Assicurazioni)

Fabio Bandini, on behalf of SIN (Società Italiana di Neurologia)

Roberto Bortolotti, on behalf of SIR (Società Italiana di Reumatologia)

Viviana Rosati, on behalf of SIRN (Società Italiana di Riabilitazione Neurologica)

Armando Perrotta, on behalf of SISC (Società Italiana per lo Studio delle Cefalee)

Gianfranco Lamberti, on behalf of SIUD (Società Italiana di Urodinamica)

Monica Pierattelli, on behalf of SICuPP (Societa' Italiana Delle Cure Primarie Pediatriche)

Giancarlo Tancredi, on behalf of SIP (Società Italiana di Pediatria).

ABSTRACT: 272 words

Objective: A shared consensus on safety about Physical Agent Modalities (PAMs) in physiotherapy and rehabilitation is lacking. We aimed to develop evidence-informed and consensus-based indications 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 - AIFI) to identify areas and questions for developing indications about the safety of the most commonly used PAMs in physiotherapy and rehabilitation. We invited 28 National Scientific and Technical Societies (STS), including forensics and lay members, as a multidisciplinary and multi-professional panel of experts to evaluate the proposed indications and formulate additional inputs. The level of agreement was measured with a 9-point Likert scale. Consensus in the Delphi rounds was assessed using the rating proportion with a threshold of 75%.

Results: Seventeen (61%) out of 28 STS participated, involving their most representative members. Experts composing the panel were mainly clinicians (88%) reporting multiple 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 indications about the safety in adult patients on nine PAMs (i.e., electrical stimulation neuromodulation, extracorporeal shock wave therapy, laser therapy, electromagnetic therapy, diathermy, hot thermal agents, cryotherapy and therapeutic ultrasound) with a general note about populations subgroups.

Conclusions: The resulting consensus-based indications inform patients, healthcare professionals and policy-makers regarding the safe application of PAMs in physiotherapy and rehabilitation. Future research is needed to extend this consensus on pediatric and frail patients.

Key Words: Physical Therapy Modalities, Safety, Rehabilitation, Physical and Rehabilitation Medicine, Delphi Technique, Orthopedics, Neurology, Pelvic Floor, Musculoskeletal System

STRENGTH AND LIMITATIONS

- We developed a national electronic survey based on a Rand Delphi technique aiming to identify, assess and modify indications for safe Physical Agent Modalities (PAMs) in rehabilitation.
- Starting from a recent scoping review of the literature we refined evidence-informed indications of rehabilitation for safe PAMs;
- The multi-professional and multidisciplinary panel of experts rated and revised the agreement of indications for safe PAMs rehabilitation in multiple rounds until reaching consensus.
- Indications were restricted to PAMs safety, not addressing their clinical effectiveness.

INTRODUCTION

Physical agent modalities (PAMs) are extensively applied in physiotherapy and rehabilitation to elicit therapeutic effects on tissues, including reducing swelling, alleviating pain, expediting the healing process, and improving muscle tone.(1-4) Healthcare professionals from diverse medical specialties can recommend and administer these treatments alongside other physiotherapy and rehabilitation interventions. However, clinicians and patients must be informed about the safety of the proposed treatments. Previous consensus regarding contraindications and precautions associated with using PAMs from various organizations were released in the early 2000s.(5-7) Still, they have become outdated in light of technological advancements of the last years.(8, 9) A recent scoping review of the literature(10) examined several systematic reviews on the safety of commonly used PAMs (i.e., cryotherapy, electrical stimulation, transcutaneous electrical nerve stimulation, functional electrical stimulation, extracorporeal shockwave therapy, laser therapy, magnetotherapy, pulsed electromagnetic field and diathermy), revealing no important harm associated with their use. Nevertheless, it is worth noting that adverse events may be underreported 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 indications about the safety of PAMs through a RAND Delphi procedure. Our goal is to make patients, healthcare professionals and policy-makers 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) 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" (CREDES).(16, 17) This project is exempted from ethical approval according to the "ethics and data protection" regulations of the European Commission.(18) More details are reported in **Supplementary File 1**. The protocol was *a-priori* registered on the Open Science Framework (OSF) online repository.(19)

The process consisted of four phases: (i) establishment of the steering committee and invitation of national scientific and technical societies (STS) to constitute the panel of experts; (ii) generation of indications using a comprehensive approach based on a published scoping review of existing systematic reviews on PAMs safety in physiotherapy and rehabilitation medicine(10) as well as on expertise from content experts of the steering committee; (iii) voting of indications from the panel of experts through a national Delphi survey aiming to identify, assess and modify indications importance for each field (e.g., musculoskeletal); (iv) an online workshop meeting to finalize the list of indications reaching the final consensus. Finally, we planned to disseminate the final indications list as good clinical practice (**Figure 1**).

[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 indications of safe PAMs, selecting national STS for expert participants, developing the Delphi questionnaires, and analyzing 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 STS in Italy for the physiotherapy profession recognized 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, EP), three on rehabilitation of musculoskeletal disorders (GR, VG, SB), one on neurological physiotherapy and neuroscience (AT), one on pelvic floor rehabilitation (AF), and four methodologists (SGa, SGi, GC, 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 multi-professional STS involved in physiotherapy and rehabilitation care (n=26) and the STS dealing with forensics (n=1). These STS were identified from the published endorsed by the Italian Ministry of Health and are recognized as the ones entitled to generate national clinical practice guidelines.(21, 22) Each STS 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 multi-professional, including clinicians, researchers, and healthcare managers from different fields(24) (e.g., orthopedics, neurology). To represent patients' perspectives, the panel also included a lay member from Cittadinazattiva,(25) the largest Italian patient advocate organization 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 indications**

The steering committee formulated indications ensuring that all the potentially relevant topics in the field would be included in the initial list of questions for the first Delphi round. Each indication 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

Supplementary File 2 reported details about each included PAM.

Indications were developed for different target conditions/populations. PAMs are delivered by expert healthcare professionals (who had undergone formal education and training) to ensure patient safety in inpatient and outpatient settings. Indications 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. Evidence was recently summarized in a scoping review(10), which gathered information about the safety of PAMs from 117 systematic reviews in physiotherapy and rehabilitation medicine. Clinical expertise was assured by content experts of AIFI (e.g., musculoskeletal disorders, orthopedic and neurological physiotherapy and pelvic floor rehabilitation).

Phase III. Voting of indications through Delphi Rounds

We used 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 the panel of experts using the SurveyMonkey online platform (Palo Alto, CA, USA; www.surveymonkey.com) and used a blinded electronic voting.

The web-based survey consisted of two sections: the first regarded the participants' demographics (e.g., type of profession, the field of expertise, and years of experience), and the second covered how to vote for indications. The panel of experts evaluated the proposed indications and formulated additional comments using a free text box to ensure complete topic coverage. According to the RAND method, the panel of experts used a 9-point Likert scale (i.e., 1-3 = highly inappropriate, 4-6 = undecided, 7-9 = highly appropriate) for rating the level of concordance for each indication.

In addition, the experts could abstain from voting, selecting the answer "Not my expertise" for indications they were not familiar with.

A summary of results for each Delphi round was provided according to the total number of experts voting as feedback to inform panel members on consensus development with feedback and descriptive statistics incorporated for the next round. The panel of experts were asked to re-rate their evaluation in more rounds only for those indications needing clarification or for indications for which consensus (i.e., ≥ 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 indication with all additional comments provided in the free text box. Based on previous voting, indications were modified and presented for the next round. Up to three reminder emails for completion were sent to each component 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 indications according to each expert contribution and to confirm which indications would be included in the final criteria list. Finally, the panel of experts was asked to vote on the final indications 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) Particularly:

1. Consensus in: ≥ 75% of participants scored the item as "critical" (score 7 to 9), and < 15% scored the item as of "limited importance" (score 1 to 3)
2. Consensus out: ≥ 75% of participants scored the item as of "limited importance" (score 1 to 3), and < 15% scored the item as "critical" (score 7 to 9)
3. No consensus: All other results.

Statistical Analysis

Descriptive statistics were used to describe general characteristic of participants, summarised as mean and standard deviation (SD) or median and interquartile range (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 indications.

RESULTS

Participants

Out of the 28 STS/organizations that were invited as panel of experts, two declined their interest in participation, while nine did not provide a response. Finally, 17 STS/organizations (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 specialized in areas such as pelvic floor (23.5%), neurological (17.6%), lymphatic disorders (5.9%), pediatrics (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 (interquartile range [IQR]: 17-36) in their respective fields. All general characteristics are reported in **Table 1.** No conflict of interest was present (**Supplementary File 3**).

[Figure 2]

[Table 1]

Delphi rounds

Two rounds of Delphi were necessary to reach a consensus.

Round 1

Overall, 17 experts panel participants completed the survey. All indications passed the first round with a consensus of 75% (**Table 2**). Five experts offered justifications for their choices (e.g., examples of clinical practice) and gave important inputs for the indications. In particular, they raised concerns about the safe use of PAMs in children. Additionally, they suggested refining the purpose of the indications, emphasizing that the focus was on patient safety rather than provider safety.

[Table 2]

Round 2

Indications of Round 1 were reviewed according to panel comments for the subsequent assessment in Round 2, with a specific restriction on the adult population and a clearer emphasis on patient safety. Overall, 14 experts panel participants (82%) completed the survey of Round 2, and all the indications passed with a consensus out of 75%. (**Table 2**). One expert provided additional comments that included examples of expertise, which were subsequently integrated into the final list of indications.

Workshop Meeting

On September 27, 2022, nine experts panel participants (53%) joined the online meeting to discuss comments, justifications and highlights. A comprehensive digital presentation of Round 1 and Round 2 findings were reported during the workshop. Here, the panel of experts suggested introducing a general note making explicit that indications on safety were not extended to different subgroups of the population (e.g., children, adolescents, frails) due to lack of literature.

The final list of indications with this general note was shared to reach final approval. All 17 experts panel participants (100%) approved and released the final indications list. One expert voted for the option "Not my expertise" in the indication of the cryotherapy (**Table 2**). In **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, clinical conditions or population settings.

DISCUSSION

Main findings

This study aimed to develop indications about the safety of PAMs in physical therapy and rehabilitation medicine. These indications were developed by a steering committee (including clinical and methodological experts) of AIFI and informed by 17 national STS with high expertise in different fields related to physiotherapy and rehabilitation (e.g., orthopedics, neurology), including a forensic scientist and a lay member in the representation of patients.

The response rate was 61%, defined as a moderate participation.(28) All nine indications were approved in the first round, achieving an important consensus of over 75% agreement. Subsequent adjustments were made, particularly regarding age restrictions (i.e., limited to the adult population) and the refinement of expertise examples during a second round. After a workshop meeting, a general note was added to clarify that the use of PAMs should not be extended to specific population subgroups. All panel experts approved and released the final indications list with overall consensus. In summary, experts agreed on the safety of PAMs in the adult population (>18 years) when prescribed and applied by a healthcare professional (e.g., physiotherapist, physician) who is formed and informed, as required by education and licensure.

Comparison with literature

This Delphi represents the most recent consensus on the safety of PAMs. Earlier consensus documents from different organizations were published in 2001,(5) 2006, (6) and 2010.(7) The Canadian guideline is the most comprehensive, covering contraindications and precautions for various PAMs. It involved experts from Canada and the United States, drawing on scientific evidence from multiple sources (including textbooks). However, it is important to note that the evidence was not collected by a clear and rigorous systematic process, potentially missing relevant information, and all these documents could be now outdated. Ideally, guidelines should be updated every three to five years or when new information become available.(29, 30) In 2018, the American Occupational

Therapy Association issued a position paper(31) 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 (e.g., ESWT (32)). Many other societies, such as National Institute for Clinical Excellence (NICE), also offer specific clinical questions guidelines, and we cannot exclude that they can involve recommendations on PAMs (e.g., NG59 for low back pain(33)).

Implications for clinicians

Healthcare professionals are encouraged to use a comprehensive approach when using this Delphi consensus. Before proposing PAMs to patients, they must collect their medical history (e.g., comorbidities) during the initial examination to better determine the diagnosis, prognosis, anticipated goals, and expected outcomes for identified impairments, activity limitations, and participation restrictions.(34) Then, they should incorporate the best research evidence, their clinical expertise, and patient values, needs, and preferences to propose effective treatments, balancing effectiveness and safety and informing patients about the possibility of trivial adverse events. For instance, a patient needing ESWT (as additional therapy to optimize clinical outcomes) should be informed about the possible occurrence of pain and erythema(10) at the application site. However, when evidence is lacking or moderate to severe harm is likely, caution is advised, and using PAM may be reconsidered. In fact, for safety purposes, developed indications were not generally extended to other subgroups, such as children, adolescents, and frail people, since limited and insufficient literature on harm is available. Some PAMs could influence the biological tissues in the growth phase in children and adolescents(35). This population has open growth plates, and their ligaments are stronger than the bony attachment sites, where they serve as connectors.(36) As a safety principle, decision-makers adopt precautionary measures when scientific evidence on harms is uncertain, and the population is vulnerable(37) (38, 39) (e.g., people historically considered at risk for being misused in clinical research or for whom a truly voluntary decision may be compromised from a regulatory perspective

such as children or frail people). All these indications should be adhered to in conjunction with the guidelines and standards established by professional associations, equipment manufacturers' manuals and regulatory bodies.(40)

Implications for stakeholders

Good practices for the safety of patients should be managed by national agencies with a living monitoring system and shared in international initiatives such as the WHO Global Patient Safety Challenge Medication Safety(41) to strengthen systems and practices adopting corrective action within countries. Our consensus could be implemented into the Good Clinical Practices (GCPs) of the Italian Ministry of Health system by Istituto Superiore di Sanità (ISS) for the production of national guidelines and the National Agency for Regional Health Services (Agenzia Nazionale per i Servizi Sanitari Regionali – AGENAS)(42) for reporting any experience of improvement in patient safety made by healthcare organizations. National and international STS should facilitate disseminating CPG in different strategies. On the one hand, STS can promote local experiences of improvement in patient safety stored in shared repository (i.e., AGENAS)(42) in the light of evidence-based consensus (e.g., SAFE PAMP) to facilitate national collaboration between different institutions.

On the other hand, STS can disseminate a plain, patient-oriented version of good clinical practice indications. We planned to develop patient and stakeholder versions of our evidence-informed and consensus-based indications. We aim to use a conceptual framework based on public health digitalization to put people and patients at the center of care delivery, supporting patient empowerment and making the healthcare system more efficient and safer.(43, 44) For example, we can plan stakeholder meetings, webinars, and education and counseling via pamphlets/videos/and social messages.

Implications for research

We believe that indications developed by the multidisciplinary and multi-professionally panel of experts can be generalized worldwide. These results could provide essential information for GCPs to produce national 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 randomized controlled trials based on the core outcome set also for harms and not only for benefit.(45) In addition, specific subgroups of populations should be studied. It is a serious matter to exclude a group from research eligibility, and this must be done only when no less restrictive option is sufficient to ensure protection from undue risk.(46)

Lastly, future studies can better explode our indications to ensure the safest and optimal modality application of the proposed PAMs (e.g., optimal voltage, amperage, frequency, current density, dose), especially for the subgroups mentioned (e.g., age of children).(47)

Strength and limitations

This is 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, 48) We adopted one of the most conservative thresholds for obtaining the consensus (75%)(27), and in all rounds, this was reached with a high percentage of agreements. However, some downsides should be acknowledged. We did not cover indications 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 with all Delphi process, our study rely on national expert response and may not capture the full range of perspectives or experiences.(16, 49) However, we tried to involve multidisciplinary and multi-professional experts (as occurs in clinical practice guidelines) that enable confrontations in anonymity (avoiding negatively influencing outcomes and encouraging balanced consideration of ideas). Then, indications were developed starting from the scoping review,

which mapped and summarized safety in population and intervention areas without assessing the evidence level (e.g., grading of the certainty of evidence).(10) For instance, panel experts were not confident about extending the indications to specific subgroups of patients (e.g., children, adolescents, frails, etc.) for precautionary reasons of the lack of literature retrieved.

CONCLUSION

These evidence-based indications inform patients, healthcare professionals, and policy-makers about the safety of a wide range of PAMs used in physiotherapy and rehabilitation after a comprehensive clinical evaluation of patients' needs. This consensus can provide a basis for decision-making and future research.

DECLARATIONS

Author Contributions

Concept/idea/research design: S. Gianola, S. Bargeri, G. Castellini

Writing: S. Gianola, S. Bargeri, G. Castellini

Data collection: S. Gianola, S. Bargeri

Data analysis: S. Gianola, S. Bargeri

Project management: S. Gianola, S. Bargeri

Consultation (including review of manuscript before submitting): S. Gianola, S. Bargeri, L. Pellicciari, S. Gambazza, G. Rossettini, A. Fulvio, V. Genovese, M. Benedini, E. Proverbio, S. Cecchetto, G. Castellini, A. Turolla, and SAFE PAMP Collaborators

Ethics Approval

This study was declared exempt from institutional review board review.

Disclosures

The authors and SAFE PAMP Collaborators declared they had no conflicts of interest.

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Data sharing statement

Research data are stored in OSF repository https://osf.io/w8kgs/ (19)

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Figure 1. Phases of the RAND Delphi process

Figure 2. Flow chart of Delphi process

Table 1. General characteristics of experts panels

Table 2. Agreement results for each round.

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Tables

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

Table 2. Agreement results for each round

Indications 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

Abbreviations: NME: not my expertise

Appendix 1. Final criteria list

Introduction

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

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

Condition/population of application: indications were presented within the relevant rehabilitation field according to *informed-evidence* and *expertise-based* consensus.

Evidence: This section has been defined on the basis of a scoping review of the literature conducted by two independent reviewers that focused on safety of PAMs from 117 systematic reviews in physiotherapy and rehabilitation medicine (10).

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

Final list of indications

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:*

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

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

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

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

  - 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:*

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

  - 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 disease.

Patients should be informed of the potential undesirable effects after applying ESWT. Indeed, a recent literature review showed some expected mild adverse events, such as pain and erythema, at the application site.(10)

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:*

  - Evidence: persistent pelvic pain and urinary incontinence.

  - 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:*

  - Evidence: rotator cuff disease, knee osteoarthritis.

  - 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:

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

  - 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:*

  - 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 physical therapies is safe in the adult population (>18 years) under the supervision of an expert operator. For precautionary reasons, these indications are not extended to other subgroups of patients (e.g., children, adolescents, frails, etc.) since insufficient literature is available.

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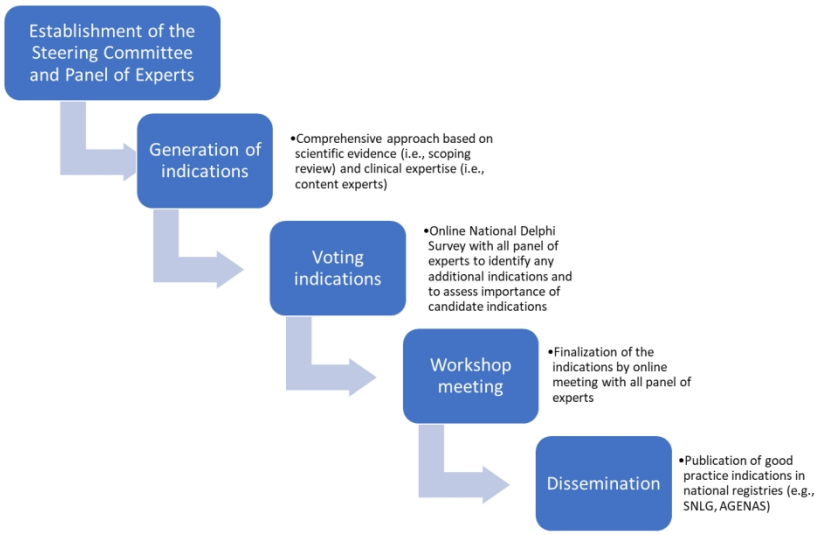

Figure 1

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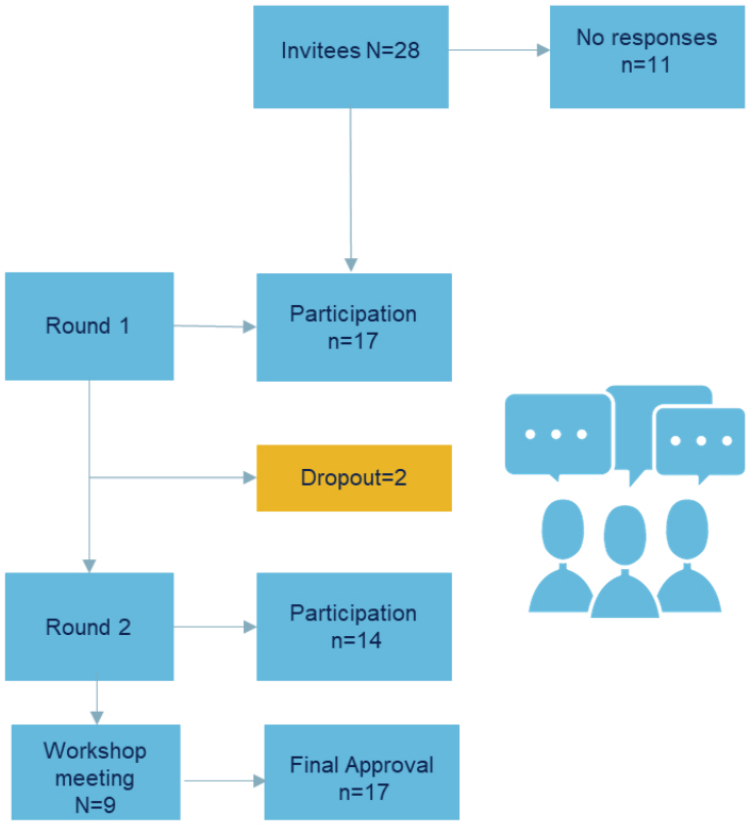

Figure 2

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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. SAFE PAMP Collaborators

Name and Surname	Affiliations	STS	COI
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 Sardegna, Cagliari, Italy	Federazione Medico Sportiva Italiana (FMSI)	None
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

Abbreviations: COI, Conflict of Interest; STS, Scientific and Technical Societies

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CREDES Checklist:

Recommendations for the Conducting and REporting of DElphi Studies (CREDES)[1]

Technology in Palliative Care (TIP): the identification of digital priorities for palliative care research using a modified Delphi method

Items of reporting	Reported on page
Purpose and rationale. The purpose of the study should be clearly defined and demonstrate the appropriateness of the use of the Delphi technique as a method to achieve the research aim. A rationale for the choice of the Delphi technique as the most suitable method needs to be provided.	5 - 6
Expert panel. Criteria for the selection of experts and transparent information on recruitment of the expert panel, sociodemographic details including information on expertise regarding the topic in question, (non)response and response rates over the ongoing iterations should be reported.	7
Description of the methods. The methods employed need to be comprehensible; this includes information on preparatory steps (How was available evidence on the topic in question synthesised?), piloting of material and survey instruments, design of the survey instrument(s), the number and design of survey rounds, methods of data analysis, processing and synthesis of experts' responses to inform the subsequent survey round and methodological decisions taken by the research team throughout the process.	7-10
Procedure. Flow chart to illustrate the stages of the Delphi process, including a preparatory phase, the actual 'Delphi rounds', interim steps of data processing and analysis, and concluding steps.	6-9; Figure 1-2
Definition and attainment of consensus. It needs to be comprehensible to the reader how consensus was achieved throughout the process, including strategies to deal with non-consensus.	9-10
Results. Reporting of results for each round separately is highly advisable in order to make the evolving of consensus over the rounds transparent. This includes figures showing the average group response, changes between rounds, as well as any modifications of the survey instrument such as deletion, addition or modification of survey items based on previous rounds.	11-12; Table 2; Appendix 2
Discussion of limitations. Reporting should include a critical reflection of potential limitations and their impact of the resulting guidance.	15-16
Adequacy of conclusions. The conclusions should adequately reflect the outcomes of the Delphi study with a view to the scope and applicability of the resulting practice guidance.	16
Publication and dissemination. The resulting guidance on good practice in palliative care should be clearly identifiable from the publication, including recommendations for transfer into practice and implementation. If the publication does not allow for a detailed presentation of either the resulting practice guidance or the methodological features of the applied Delphi technique, or both, reference to a more detailed presentation elsewhere should be made (e.g. availability of the full guideline from the authors or online; publication of a separate paper reporting on methodological details and particularities of the process (e.g. persistent disagreement and controversy on certain issues)). A dissemination plan should include endorsement of the guidance by professional associations and health care authorities to facilitate implementation.	13-14

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BMJ Open

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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Secondary Subject Heading:	Rehabilitation medicine, Rheumatology, Sports and exercise medicine, Neurology, Urology
Keywords:	Physical Therapy Modalities, REHABILITATION MEDICINE, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, ORTHOPAEDIC & TRAUMA SURGERY, NEUROLOGY

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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

Authors List

Silvia Gianola[1], Silvia Bargeri[1], Leonardo Pellicciari[2], Simone Gambazza[3], Giacomo Rossettini[4,5,6], Anna Fulvio[7], Vincenzo Genovese[7], Matteo Benedini[7], Emanuele Proverbio[7], Simone Cecchetto[7,8], Greta Castellini[1], Andrea Turolla [9,10] and SAFE PAMP Collaborators*

1. IRCCS Istituto Ortopedico Galeazzi, Unit of Clinical Epidemiology, Milan, Italy
2. IRCCS Istituto delle Scienze Neurologiche di Bologna, Bologna, Italy
3. Healthcare Professions Department, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy
4. School of Physiotherapy, University of Verona, Verona, Italy
5. Department of Human Neurosciences, University of Roma "Sapienza Roma", Rome, Italy
6. Department of Physiotherapy, Faculty of Sport Sciences, Universidad Europea de Madrid, Calle Tajo s/n, Villaviciosa de Odón 28670, Spain
7. Associazione Italiana di Fisioterapia (AIFI), Rome, Italy
8. Direction of Health Professions, APSS, 38014 Trento, Italy.
9. Department of Biomedical and Neuromotor Sciences-DIBINEM, Alma Mater Studiorum Università di Bologna, 40138 Bologna, Italy.
10. Unit of Occupational Medicine, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy

Corresponding author:

Silvia Bargeri

IRCCS Istituto Ortopedico Galeazzi, Unit of Clinical Epidemiology, Milan, Italy

silvia.bargeri@grupposandonato.it

*co-last

SAFE PAMP Collaborators

Chiara Torresetti, on behalf of AIUG (Associazione Italiana di Urologia Ginecologia e del Pavimento Pelvico)

Bianca Masturzo, on behalf of AOGOI (Associazione Ostetrici Ginecologi Ospedalieri Italiani)

Carla Berliri, on behalf of Cittadinanzattiva Associazione di Promozione Socialez

Mauro Roselli, on behalf of OTODI (Ortopedici e Traumatologi Ospedalieri D'Italia)

Stefano Vercelli, on behalf of FIASF (Federazione Italiana delle Associazioni Scientifiche di Fisioterapia)

Marco Scorcu, on behalf of FMSI (Federazione Medico Sportiva Italiana)

Giuseppe Botta, on behalf of SIFL (Società Italiana di Flebolinfologia)

Luigi Nappi, on behalf of SIGO (Società Italiana Di Ginecologia E Ostetricia)

Gianmarco Rea, on behalf of SIMG (Società Italiana di Medicina Generale e delle cure primarie)

Enrico Marinelli, on behalf of SIMLA (Società Italiana di Medicina Legale e delle Assicurazioni)

Fabio Bandini, on behalf of SIN (Società Italiana di Neurologia)

Roberto Bortolotti, on behalf of SIR (Società Italiana di Reumatologia)

Viviana Rosati, on behalf of SIRN (Società Italiana di Riabilitazione Neurologica)

Armando Perrotta, on behalf of SISC (Società Italiana per lo Studio delle Cefalee)

Gianfranco Lamberti, on behalf of SIUD (Società Italiana di Urodinamica)

Monica Pierattelli, on behalf of SICuPP (Societa' Italiana Delle Cure Primarie Pediatriche)

Giancarlo Tancredi, on behalf of SIP (Società Italiana di Pediatria).

ABSTRACT: 280 words

Objective: A shared consensus on safety about Physical Agent Modalities (PAMs) pratice 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 - AIFI) 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 multi-professional panel of experts to evaluate the nine proposed statements and formulate additional inputs. The level of agreement was measured with a 9-point Likert scale. Consensus in the Delphi rounds was assessed using the rating proportion with a threshold of 75%.

Results: Seventeen (61%) out of 28 Scientific and Technical Societies participated, involving their most representative members. Experts composing the panel were mainly clinicians (88%) reporting multiple 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 in adult patients on nine PAMs (i.e., electrical stimulation neuromodulation, extracorporeal shock wave therapy, laser therapy, electromagnetic therapy, diathermy, hot thermal agents, cryotherapy and therapeutic ultrasound) 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 pediatric and frails such as immunocompromised patients.

Key Words: Physical Therapy Modalities, Safety, Rehabilitation, Physical and Rehabilitation Medicine, Delphi Technique, Orthopedics, Neurology, Pelvic Floor, Musculoskeletal System

STRENGTH AND LIMITATIONS

- Starting from a recent scoping review of the literature, we aimed to acknowledge evidence-informed indications of rehabilitation for safe 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 multi-professional 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 to elicit therapeutic effects on tissues, including reducing swelling, alleviating pain, expediting the healing process, and improving muscle tone.(1-4) Healthcare professionals from diverse medical specialties can recommend and administer these treatments alongside other physiotherapy and rehabilitation interventions. However, clinicians and patients must be informed about the safety of the proposed treatments. Previous consensus regarding contraindications and precautions associated with using PAMs from various organizations were released in the early 2000s.(5-7) Still, they have become outdated in light of technological advancements of the last years.(8, 9) A recent scoping review of the literature(10) examined several systematic reviews on the safety of commonly used PAMs (i.e., cryotherapy, electrical stimulation, transcutaneous electrical nerve stimulation, functional electrical stimulation, extracorporeal shockwave therapy, laser therapy, magnetotherapy, pulsed electromagnetic field and diathermy), revealing no important harm associated with their use. Nevertheless, it is worth noting that adverse events may be underreported 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 policy-makers 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) 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" (CREDES).(16, 17) This project is exempted from ethical approval according to the "ethics and data protection" regulations of the European Commission.(18) More details are reported in **Supplementary File 1**. The protocol was *a-priori* registered on the Open Science Framework (OSF) online repository.(19)

The process consisted of four phases: (i) establishment of the steering committee and invitation of national scientific and technical societies to constitute the panel of experts; (ii) 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(10) as well as on expertise from content experts of the steering committee; (iii) rating of statements from the panel of experts through a national Delphi survey aiming to identify, assess and modify statements importance for each field (e.g., musculoskeletal); (iv) an online workshop meeting to finalize the list of statements reaching the final consensus. Finally, we planned to disseminate the final statements list as good clinical practice (**Figure 1**).

[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 analyzing 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 societies in Italy for the physiotherapy profession recognized 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, EP), three on rehabilitation of musculoskeletal disorders (GR, VG, SB), one on neurological physiotherapy and neuroscience (AT), one on pelvic floor rehabilitation (AF), and four methodologists (SGa, SGi, GC, 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 multi-professional 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 recognized 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 multi-professional, including clinicians, researchers, and healthcare managers from different fields(24) (e.g., orthopedics, neurology). To represent patients' perspectives, the panel also included a lay member from Cittadinazattiva,(25) the largest Italian patient advocate organization 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**

Firstly, the steering committee formulated statements aimed at safety based on evidence and clinical expertise. Particularly, evidence was summarized from a published scoping review and its supplementary materials,(10) which gathered information about the safety of the nine PAMs from 117 systematic reviews in physiotherapy and rehabilitation medicine (e.g. safety of PAMs for low back pain, osteoarthritis, stroke, urinary incomitance). Clinical expertise was assured by content experts of AIFI (e.g., musculoskeletal disorders, orthopedic 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 **(Supplementary 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 used 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 the panel of experts using the SurveyMonkey online platform (Palo Alto, CA, USA; www.surveymonkey.com) and used a blinded electronic rating.

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

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

A summary of results for each Delphi round was provided according to the total number of experts rating as feedback to inform panel members on consensus development with feedback and descriptive statistics incorporated for the next round. The panel of experts were asked to re-rate their evaluation in more rounds only for those statements needing clarification or for statements for which consensus (i.e., ≥ 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 with all additional comments provided in the free text box. Based on previous rating, statements were modified and presented for the next round. Up to three reminder emails for completion were sent to each component 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 contribution and to confirm which statements would be included in the final criteria list. Finally, the panel of experts was asked to rate on 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) Particularly:

1. Consensus in: ≥ 75% of participants scored the item as "highly appropriate" (score 7 to 9), and < 15% scored the item as of "highly inappropriate" (score 1 to 3)
2. Consensus out: ≥ 75% of participants scored the item as of "highly inappropriate" (score 1 to 3), and < 15% scored the item as "highly appropriate" (score 7 to 9)
3. No consensus: All other results.

Statistical Analysis

Descriptive statistics were used to describe general characteristic of participants, summarised as median and interquartile range (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/organizations that were invited as panel of experts, two declined their interest in participation, while nine did not provide a response. Finally, 17 societies/organizations (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 specialized in areas such as pelvic floor (23.5%), neurological (17.6%), lymphatic disorders (5.9%), pediatrics (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 (**Supplementary File 3**).

[Figure 2]

[Table 1]

Delphi rounds

Two rounds of Delphi 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 (e.g., examples of clinical practice) and gave 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, emphasizing that the focus was on patient safety rather than provider safety. Some experts reported uncertainties about safe use of PAMs according to their experiences. For examples, one expert reported the possible mild skin irritation in the hot thermal

therapies and another one suggested caution in the use of cryotherapy due to risk of cold burns, especially if the patients are not well informed or supervised. Then, one expert was uncertain about safety in persistent use of electromagnetic therapies for long-terms. Some experts suggested safe use of PAMS in other fields of applications such as the use of diathermia in the dermatological field for Lichen Sclerosus, that was out of our purposes. All comments were considered in the release of the statements (**Supplementary File 4**).

[Table 2]

Round 2

Statements of Round 1 were reviewed according to panel comments for the subsequent assessment in Round 2, with a specific restriction on the adult population and a clearer emphasis on patient safety.

1. Overall, 14 experts panel participants (participation rate: 82%) completed the survey of Round 2, and all the statements passed with a consensus out of 75%. (**Table 2**). One expert provided additional comments that included examples of expertise, which were subsequently integrated into the final list of statements. In particular, low level laser therapy could accentuate genital dryness, requiring additional interventions to improve hydration during the treatment period to mitigate certain discomfort to the patients. For other therapies, such as electrical stimulation and extracorporeal shock wave therapy there was uncertainty of applications in some field due to little expertise (Supplementary File 4).

Workshop Meeting

On September 27, 2022, nine experts panel participants (completion rate: 53%) joined the online meeting to discuss comments, justifications and highlights. A comprehensive digital presentation of Round 1 and Round 2 findings were reported during the workshop. Here, the panel of experts suggested introducing a general note making explicit that statements on safety were not extended to

different subgroups of the population (e.g., children, adolescents, immunocompromised) due to lack of literature.

The final list of statements with this general note was shared via SurveyMonkey to reach final approval. All 17 experts panel participants (approval rate: 100%) approved and released the final statements list. One expert rated for the option "Not my expertise" in the statement of the cryotherapy (**Table 2**). In **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 Physical Agent Modalities 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 (e.g., 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 (e.g., physiotherapist, physician) who is formed and informed, as required by education and licensure.

Literature Context

Earlier consensus documents from different organizations were published in 2001,(5) 2006,(6) and 2010.(7) 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 (e.g., extracorporeal shock wave therapy(30)). Many other societies, such as National Institute for Clinical Excellence (NICE), also offer specific clinical questions guidelines, and we cannot exclude that they can involve recommendations on PAMs (e.g., NG59 for low back pain(31)).

Overall, the Canadian document(7) 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 (e.g. field) sustained by literature and clinical expertise. This does not mean that the contraindications and precautions mentioned in the Canadian guideline(7) are in contrast to our findings. Simply, we use a complementary perspective. Our Delphi agree 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 recognize 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 United States 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 three to five 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. Before proposing PAMs to patients, they must collect their medical history (e.g., 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 and informing patients about the possibility of trivial adverse events (e.g., pain and erythema at the application site(10) using extracorporeal shock wave therapy). However, when evidence is lacking and moderate to severe harm is likely, caution is advised, and using PAM may be reconsidered. In fact, for precautionary purpose. (35-37) 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 people (e.g., immunocompromised patients), since limited and insufficient literature on harm is available. Generally, all these statements should be adhered to in conjunction with precautions and contraindications under specific circumstances referring to equipment manufacturers' manuals and

regulatory bodies(40) as well as to previous guidelines(7) and standards established by professional associations.

Implications for stakeholders

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

Implications for research

We believe that statements developed by the multidisciplinary and multi-professionally panel of experts can be generalized worldwide. These results could provide essential information to produce national (e.g., 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 randomized controlled trials based on the core outcome set also for harms and not only for benefit.(46) In addition, specific subgroups of populations should be studied. It is a serious matter to exclude a group from research eligibility, and this must be done only 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 optimal modality application of the proposed PAMs (e.g., optimal voltage, amperage, frequency, current density, dose), contraindications and precautions, especially for the subgroups mentioned (e.g., children, immunocompromised people).(48)

Strength and limitations

This is 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 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 (e.g., active deep vein thrombosis). In addition, evidence-informed by systematic reviews did not find enough information about risk for a specific population (e.g., hemato-oncological patients with severe immunocompromised or coagulopathy). However, based on the principle of precaution, the panel agreed to add as a general note about precaution 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) However, we tried to involve multidisciplinary and multi-professional experts (as occurs in clinical practice guidelines) that enable confrontations in anonymity (avoiding negatively influencing outcomes and encouraging balanced consideration of ideas). Then, statements were developed starting from the scoping review(10), which mapped and summarized safety in population and intervention areas without

assessing the certainty of evidence (e.g., grading of the certainty of evidence).(10) Lastly, even if we generated statements starting from the latest available evidence, we should recognize that adverse events may be under-estimated since safety outcome is commonly poor-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 field and conditions of physiotherapy and rehabilitation practice after a comprehensive clinical evaluation of patients' needs. All 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.

DECLARATIONS

Author Contributions

Concept/idea/research design: S. Gianola, S. Bargeri, G. Castellini

Writing: S. Gianola, S. Bargeri, G. Castellini

Data collection: S. Gianola, S. Bargeri

Data analysis: S. Gianola, S. Bargeri

Project management: S. Gianola, S. Bargeri

Consultation (including review of manuscript before submitting): S. Gianola, S. Bargeri, L. Pellicciari, S. Gambazza, G. Rossettini, A. Fulvio, V. Genovese, M. Benedini, E. Proverbio, S. Cecchetto, G. Castellini, A. Turolla, and SAFE PAMP Collaborators

Ethics Approval

This study was declared exempt from institutional review board review.

Disclosures

The authors and SAFE PAMP Collaborators declared they had no conflicts of interest.

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Data sharing statement

Research data are stored in OSF repository https://osf.io/w8kgs/ (19)

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Figure 1. Phases of the RAND Delphi process

Figure 2. Flow chart of Delphi process

Table 1. General characteristics of experts panels

Table 2. Agreement results for each round.

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Tables

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

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

Abbreviations: NME: not my expertise

Appendix 1. Final criteria list

Introduction

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

Target group: statements were developed for adults (> 18 years). Physical agents modalities 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 on the basis of a scoping review of the literature conducted by two independent reviewers that focused on safety of PAMs from 117 systematic reviews in physiotherapy and rehabilitation medicine (10).

Expertise: this section has been formulated by the steering committee which included different content experts of 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:*

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

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

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

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

  - 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:*

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

  - 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 after applying ESWT. Indeed, a recent literature review showed some expected mild adverse events, such as pain and erythema, at the application site.(10)

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 physical therapies 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.

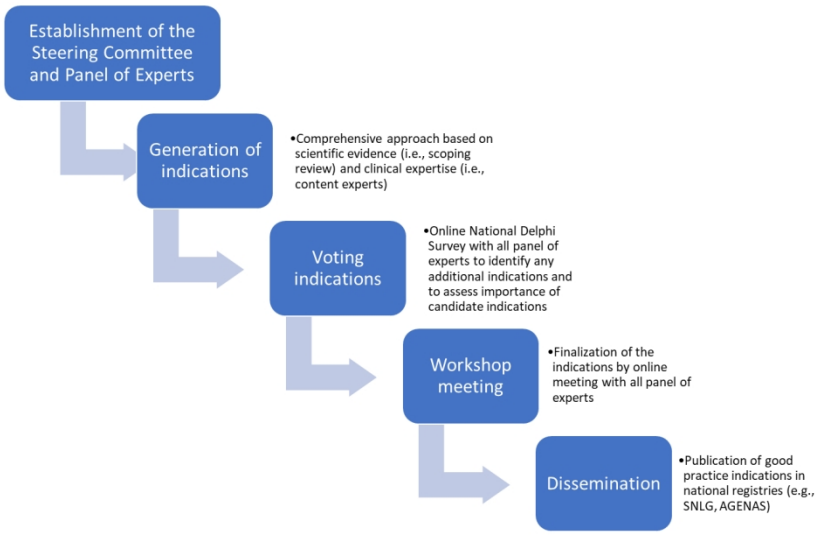

Figure 1

282x150mm (150 x 150 DPI)

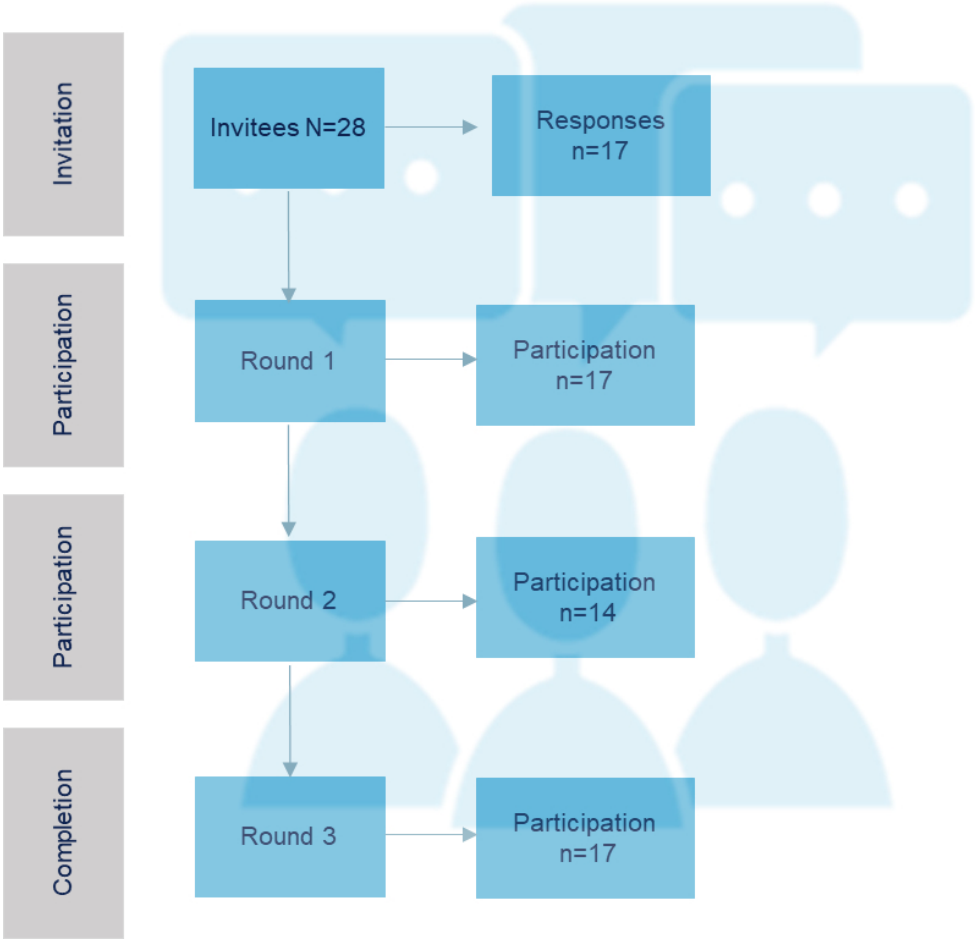

Figure 2

138x140mm (150 x 150 DPI)

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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CREDES Checklist:

Recommendations for the Conducting and REporting of DElphi Studies (CREDES)[1]

Items of reporting	Reported on page
Purpose and rationale. The purpose of the study should be clearly defined and demonstrate the appropriateness of the use of the Delphi technique as a method to achieve the research aim. A rationale for the choice of the Delphi technique as the most suitable method needs to be provided.	5 - 6
Expert panel. Criteria for the selection of experts and transparent information on recruitment of the expert panel, sociodemographic details including information on expertise regarding the topic in question, (non)response and response rates over the ongoing iterations should be reported.	7
Description of the methods. The methods employed need to be comprehensible; this includes information on preparatory steps (How was available evidence on the topic in question synthesised?), piloting of material and survey instruments, design of the survey instrument(s), the number and design of survey rounds, methods of data analysis, processing and synthesis of experts' responses to inform the subsequent survey round and methodological decisions taken by the research team throughout the process.	7-10
Procedure. Flow chart to illustrate the stages of the Delphi process, including a preparatory phase, the actual 'Delphi rounds', interim steps of data processing and analysis, and concluding steps.	6-9; Figure 1-2
Definition and attainment of consensus. It needs to be comprehensible to the reader how consensus was achieved throughout the process, including strategies to deal with non-consensus.	9-10
Results. Reporting of results for each round separately is highly advisable in order to make the evolving of consensus over the rounds transparent. This includes figures showing the average group response, changes between rounds, as well as any modifications of the survey instrument such as deletion, addition or modification of survey items based on previous rounds.	10-12; Table 2; Appendix 2
Discussion of limitations. Reporting should include a critical reflection of potential limitations and their impact of the resulting guidance.	15-16
Adequacy of conclusions. The conclusions should adequately reflect the outcomes of the Delphi study with a view to the scope and applicability of the resulting practice guidance.	16
Publication and dissemination. The resulting guidance on good practice in palliative care should be clearly identifiable from the publication, including recommendations for transfer into practice and implementation. If the publication does not allow for a detailed presentation of either the resulting practice guidance or the methodological features of the applied Delphi technique, or both, reference to a more detailed presentation elsewhere should be made (e.g. availability of the full guideline from the authors or online; publication of a separate paper reporting on methodological details and particularities of the process (e.g. persistent disagreement and controversy on certain issues)). A dissemination plan should include endorsement of the guidance by professional associations and health care authorities to facilitate implementation.	13-14

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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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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

Authors List

Silvia Gianola[1], Silvia Bargeri[1], Leonardo Pellicciari[2], Simone Gambazza[3], Giacomo Rossettini[4,5,6], Anna Fulvio[7], Vincenzo Genovese[7], Matteo Benedini[7], Emanuele Proverbio[7], Simone Cecchetto[7,8], Greta Castellini[1], Andrea Turolla [9,10] and SAFE PAMP Collaborators*

1. IRCCS Istituto Ortopedico Galeazzi, Unit of Clinical Epidemiology, Milan, Italy
2. IRCCS Istituto delle Scienze Neurologiche di Bologna, Bologna, Italy
3. Healthcare Professions Department, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy
4. School of Physiotherapy, University of Verona, Verona, Italy
5. Department of Human Neurosciences, University of Roma "Sapienza Roma", Rome, Italy
6. Department of Physiotherapy, Faculty of Sport Sciences, Universidad Europea de Madrid, Calle Tajo s/n, Villaviciosa de Odón 28670, Spain
7. Associazione Italiana di Fisioterapia (AIFI), Rome, Italy
8. Direction of Health Professions, APSS, 38014 Trento, Italy.
9. Department of Biomedical and Neuromotor Sciences-DIBINEM, Alma Mater Studiorum Università di Bologna, 40138 Bologna, Italy.
10. Unit of Occupational Medicine, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy

Corresponding author:

Silvia Bargeri

IRCCS Istituto Ortopedico Galeazzi, Unit of Clinical Epidemiology, Milan, Italy

silvia.bargeri@grupposandonato.it

*co-last

SAFE PAMP Collaborators

Chiara Torresetti, on behalf of AIUG (Associazione Italiana di Urologia Ginecologia e del Pavimento Pelvico)

Bianca Masturzo, on behalf of AOGOI (Associazione Ostetrici Ginecologi Ospedalieri Italiani)

Carla Berliri, on behalf of Cittadinanzattiva Associazione di Promozione Socialez

Mauro Roselli, on behalf of OTODI (Ortopedici e Traumatologi Ospedalieri D'Italia)

Stefano Vercelli, on behalf of FIASF (Federazione Italiana delle Associazioni Scientifiche di Fisioterapia)

Marco Scorcu, on behalf of FMSI (Federazione Medico Sportiva Italiana)

Giuseppe Botta, on behalf of SIFL (Società Italiana di Flebolinfologia)

Luigi Nappi, on behalf of SIGO (Società Italiana Di Ginecologia E Ostetricia)

Gianmarco Rea, on behalf of SIMG (Società Italiana di Medicina Generale e delle cure primarie)

Enrico Marinelli, on behalf of SIMLA (Società Italiana di Medicina Legale e delle Assicurazioni)

Fabio Bandini, on behalf of SIN (Società Italiana di Neurologia)

Roberto Bortolotti, on behalf of SIR (Società Italiana di Reumatologia)

Viviana Rosati, on behalf of SIRN (Società Italiana di Riabilitazione Neurologica)

Armando Perrotta, on behalf of SISC (Società Italiana per lo Studio delle Cefalee)

Gianfranco Lamberti, on behalf of SIUD (Società Italiana di Urodinamica)

Monica Pierattelli, on behalf of SICuPP (Societa' Italiana Delle Cure Primarie Pediatriche)

Giancarlo Tancredi, on behalf of SIP (Società Italiana di Pediatria).

ABSTRACT: 280 words

Objective: A shared consensus on the safety about Physical Agent Modalities (PAMs) pratice 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 - AIFI) 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 multi-professional 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 was assessed using the rating proportion with a threshold of 75%.

Results: Seventeen (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 (i.e., 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 pediatric and frail populations, such as immunocompromised patients.

Key Words: Physical Therapy Modalities, Safety, Rehabilitation, Physical and Rehabilitation Medicine, Delphi Technique, Orthopedics, Neurology, Pelvic Floor, Musculoskeletal System

STRENGTH AND LIMITATIONS

- Starting from a recent scoping review of the literature, we aimed to acknowledge evidence-informed indications of rehabilitation for safe 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 multi-professional 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 organizations were 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 underreported 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 policy-makers 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" (CREDES).(16, 17) This project is exempted from ethical approval according to the "ethics and data protection" regulations of the European Commission.(18) More details are reported in **Supplementary File 1**. The protocol was *a-priori* registered on the Open Science Framework (OSF) online repository.(19)

The process consisted of four phases: (i) establishment of the steering committee and invitation of national scientific and technical societies to constitute the panel of experts; (ii) 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; (iii) rating of statements from the panel of experts through a national Delphi survey aiming to identify, assess and modify statement importance for each field (e.g., musculoskeletal); (iv) an online workshop meeting to finalize the list of statements reaching the final consensus. Finally, we planned to disseminate the final statements list as good clinical practice (**Figure 1**).

[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 analyzing 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 recognized 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, EP), three on rehabilitation of musculoskeletal disorders (GR, VG, SB), one on neurological physiotherapy and neuroscience (AT), one on pelvic floor rehabilitation (AF), and four methodologists (SGa, SGi, GC, 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 multi-professional 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 recognized 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 multi-professional, including clinicians, researchers, and healthcare managers from different fields(24) (e.g., orthopedics, neurology). To represent patients' perspectives, the panel also included a lay member from Cittadinazattiva,(25) the largest Italian patient advocate organization 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**

Firstly, the steering committee formulated statements aimed at safety based on evidence and clinical expertise. Particularly, evidence was summarized from a published scoping review and its supplementary materials,(5) which gathered information about the safety of the nine PAMs from 117 systematic reviews in physiotherapy and rehabilitation medicine (e.g. safety of PAMs for low back pain, osteoarthritis, stroke, urinary incomitance). Clinical expertise was assured by content experts of AIFI (e.g., musculoskeletal disorders, orthopedic 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 **(Supplementary 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, CA, USA; www.surveymonkey.com) and utilized a blinded electronic rating.

The web-based survey comprised two sections: the first concerned the participants' demographics (e.g., 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 (i.e., 1-3 = highly inappropriate, 4-6 = undecided, 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 were asked to re-rate their evaluation in subsequent rounds only for those statements needing clarification or for statements for which consensus (i.e., ≥ 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" (score 7 to 9), and < 15% scored the item as of "highly inappropriate" (score 1 to 3)
2. Consensus out: ≥ 75% of participants scored the item as of "highly inappropriate" (score 1 to 3), and < 15% scored the item as "highly appropriate" (score 7 to 9)
3. No consensus: All other results.

Statistical Analysis

Descriptive statistics were used to describe general characteristic of participants, summarised as median and interquartile range (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/organizations that were invited as panel of experts, two declined their interest in participation, while nine did not provide a response. Finally, 17 societies/organizations (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 specialized in areas such as pelvic floor (23.5%), neurological (17.6%), lymphatic disorders (5.9%), pediatrics (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 (**Supplementary File 3**).

[Figure 2]

[Table 1]

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 (e.g., 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, emphasizing 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 (**Supplementary File 4**).

[Table 2]

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. 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 (**Supplementary File 4**).

Workshop Meeting

On September 27, 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 (e.g., 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 statement on cryotherapy (**Table 2**). In **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 Physical Agent Modalities 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 (e.g., 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 (e.g., physiotherapist, physician) who is adequately trained and informed, as required by education and licensure.

Literature Context

Earlier consensus documents from different organizations 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 (e.g., extracorporeal shock wave therapy(30)). Many other societies, such as National Institute for Clinical Excellence (NICE), also offer specific clinical questions guidelines, and we cannot exclude that they can involve recommendations on PAMs (e.g., 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 (e.g., 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 recognize 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 United States 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 three to five 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 (e.g., 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 (e.g., 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 (e.g., 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 organize meetings with stakeholders and patients, conduct webinars, and provide education and counseling through pamphlets, videos, and social media messages.

Implications for research

We believe that the statements developed by the multidisciplinary and multi-professionally panel of experts can be generalized worldwide. These results could provide essential information to produce national guidelines (e.g., 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 randomized 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 (e.g., optimal voltage, amperage, frequency, current density, dose), as well as contraindications and precautions, especially for the mentioned subgroups (e.g., 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 (e.g., active deep vein thrombosis). Furthermore, evidence-informed by systematic reviews did not find enough information about the risk for specific population (e.g., hemato-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 multi-professional 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 summarized safety in population and

intervention areas without assessing the certainty of evidence (e.g., grading of the certainty of evidence).(5) Lastly, even though we generated statements based on the latest available evidence, we should recognize that adverse events may be under-estimated 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.

DECLARATIONS

Author Contributions

Concept/idea/research design: S. Gianola, S. Bargeri, G. Castellini

Writing: S. Gianola, S. Bargeri, G. Castellini

Data collection: S. Gianola, S. Bargeri

Data analysis: S. Gianola, S. Bargeri

Project management: S. Gianola, S. Bargeri

Consultation (including review of manuscript before submitting): S. Gianola, S. Bargeri, L. Pellicciari, S. Gambazza, G. Rossettini, A. Fulvio, V. Genovese, M. Benedini, E. Proverbio, S. Cecchetto, G. Castellini, A. Turolla, and SAFE PAMP Collaborators

Ethics Approval

This study was declared exempt from institutional review board review.

Disclosures

The authors and SAFE PAMP Collaborators declared they had no conflicts of interest.

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Data sharing statement

Research data are stored in OSF repository https://osf.io/w8kgs/ (19)

Manuscript word count: 3275/4000

Figure 1. Phases of the RAND Delphi process

Figure 2. Flow chart of Delphi process

Table 1. General characteristics of experts panels

Table 2. Agreement results for each round.

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Tables

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

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

Abbreviations: NME: not my expertise

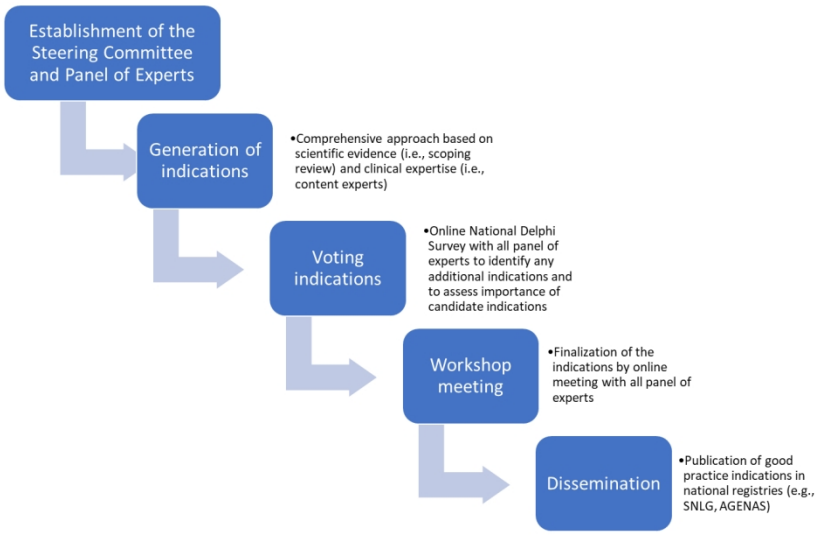

Figure 1

282x150mm (150 x 150 DPI)

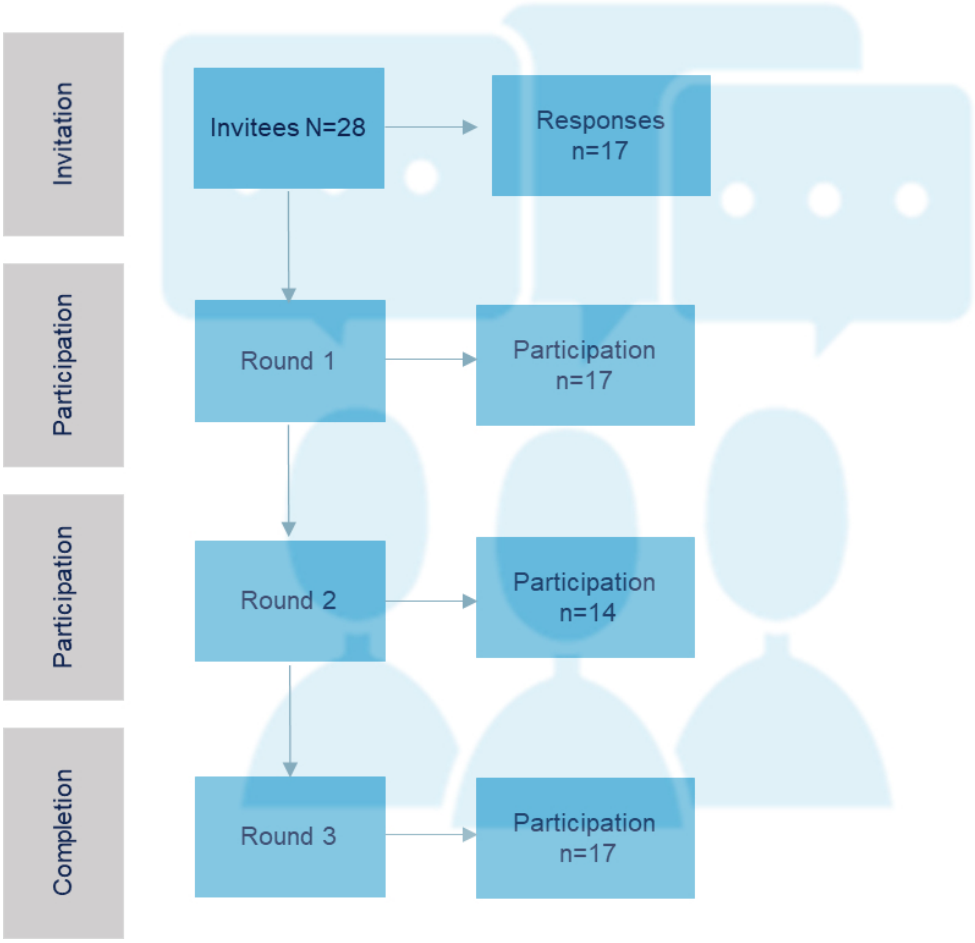

Figure 2

138x140mm (150 x 150 DPI)

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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CREDES Checklist:

Recommendations for the Conducting and REporting of DElphi Studies (CREDES)[1]

Items of reporting	Reported on page
Purpose and rationale. The purpose of the study should be clearly defined and demonstrate the appropriateness of the use of the Delphi technique as a method to achieve the research aim. A rationale for the choice of the Delphi technique as the most suitable method needs to be provided.	5 - 6
Expert panel. Criteria for the selection of experts and transparent information on recruitment of the expert panel, sociodemographic details including information on expertise regarding the topic in question, (non)response and response rates over the ongoing iterations should be reported.	7
Description of the methods. The methods employed need to be comprehensible; this includes information on preparatory steps (How was available evidence on the topic in question synthesised?), piloting of material and survey instruments, design of the survey instrument(s), the number and design of survey rounds, methods of data analysis, processing and synthesis of experts' responses to inform the subsequent survey round and methodological decisions taken by the research team throughout the process.	7-10
Procedure. Flow chart to illustrate the stages of the Delphi process, including a preparatory phase, the actual 'Delphi rounds', interim steps of data processing and analysis, and concluding steps.	6-9; Figure 1-2
Definition and attainment of consensus. It needs to be comprehensible to the reader how consensus was achieved throughout the process, including strategies to deal with non-consensus.	9-10
Results. Reporting of results for each round separately is highly advisable in order to make the evolving of consensus over the rounds transparent. This includes figures showing the average group response, changes between rounds, as well as any modifications of the survey instrument such as deletion, addition or modification of survey items based on previous rounds.	10-12; Table 2; Appendix 2
Discussion of limitations. Reporting should include a critical reflection of potential limitations and their impact of the resulting guidance.	15-16
Adequacy of conclusions. The conclusions should adequately reflect the outcomes of the Delphi study with a view to the scope and applicability of the resulting practice guidance.	16
Publication and dissemination. The resulting guidance on good practice in palliative care should be clearly identifiable from the publication, including recommendations for transfer into practice and implementation. If the publication does not allow for a detailed presentation of either the resulting practice guidance or the methodological features of the applied Delphi technique, or both, reference to a more detailed presentation elsewhere should be made (e.g. availability of the full guideline from the authors or online; publication of a separate paper reporting on methodological details and particularities of the process (e.g. persistent disagreement and controversy on certain issues)). A dissemination plan should include endorsement of the guidance by professional associations and health care authorities to facilitate implementation.	13-14

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