Evidence Based Clinical Practice Guidelines for the use of Functional Electric Stimulation to improve mobility in adults with lower limb impairment due to an upper motor neuron lesion.

Queen Margaret University and ACPIN
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1. About this document

This document describes the evidence based clinical practice recommendations for best use of Functional Electrical Stimulation (FES) to improve mobility in adults with lower limb impairment due to an upper motor neuron lesion. These guidelines are intended to inform all stakeholders, including people who may be able to benefit from using FES, people who distribute, provide, research and develop FES. They were developed in the UK with international input. The authors believe they synthesise the best evidence available following rigorous review of the literature, qualitative data collection from stakeholders and development of expert consensus. The Clinical Guideline Document has been reviewed and approved by the ACPIN Committee. It will support healthcare professionals in exercising their professional autonomy when engaging in person-centred practice with individual service users and the people in their lives. The responsibility for guideline implementation lies with local service providers and commissioners.

1.1.1 Citing this document

ACPIN Clinical Guideline Working Group. Evidence Based Clinical Guidelines for the use of Functional Electric Stimulation to Improve Mobility in Adults with lower limb impairment due to an upper motor neuron lesion. Association of Chartered Physiotherapists in Neurology: 2022 www.acpin.net.

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1.1.3 Acknowledgements

Thanks are due to the following groups (Names listed in Appendix 1): The Association for Chartered Physiotherapists in Neurology Working Group which initiated this work and Committee who reviewed the draft document; the Chartered Society of Physiotherapy Professional Network Fund which supported this work; the authors of the Overview of Systematic Reviews which informed the Clinical Practice Guidelines; survey respondents and contributors to the qualitative focus groups and interviews which informed content of the Clinical Practice Guideline; and the Delphi Panel Steering Group and Delphi Expert Panel. We have learned from the Guideline Development process and documentation developed by the British Association of Chartered Physiotherapists in Amputee Rehabilitation and referred to the "Evidence Based Clinical Guidelines for the Physiotherapy Management of Adults with Lower Limb Prostheses."

1.1.4 Comments on these guidelines should be sent to

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2. Executive Summary

The Association for Chartered Physiotherapists in Neurology (ACPIN) collaborated with Queen Margaret University and University of Southampton to develop Clinical Practice Guidelines (CPGs) focusing on use of Functional Electrical Stimulation (FES) to support mobility in adults with lower limb impairments due to upper motor neurone lesions.

The process was designed using principles of person-centred practice and considered the importance of decolonising research; equal value was given to different forms of evidence including the voices of persons of experience.

This guideline has been produced to inform all stakeholders involved with FES, including people who use FES for mobility and people in their lives, people who provide FES and who have strategic and/or leadership roles in FES services; and people who distribute, develop and research FES. Informed by consultation with stakeholders, this CPG aims to support advocacy for funding of appropriate FES provision, increased and more equal access to FES services, with greater awareness of FES services and referral criteria. Evidence is synthesised to provide guidance on optimal design and provision of FES services that includes safe and effective assessment and ongoing support and monitoring, with appropriate training of FES providers. By synthesising published evidence with stakeholder views and expert consensus the recommendations within this guideline should assist clinical decision making in collaboration with the potential/actual FES user, with full consideration of their views and preferences.

The stages of developing this CPG included:

1. Rigorous stakeholder consultation using survey and qualitative methods to find out whether people felt this CPG was needed and what it should address.
2. Evidence synthesis, carried out by conducting a systematic overview of systematic reviews regarding use of FES to support walking in people living with upper motor neurone lesions.
3. A Delphi consensus method, informed by 1. and 2., to establish consensus regarding optimal practice from people with appropriate experience and expertise; development of conclusions about what FES service provision should look like when supporting mobility for people with upper motor neurone lesions in the form of guidance statements.
4. Review of the draft CPG by the ACPIN Committee.

An implementation plan is under development, informed by stakeholder consultation and a review period for these CPGs will be determined. It is hoped that this CPG will inform research priorities and its review and revision in the future.

It is important to note that this CPG is not a legally binding document. The best evidence that could be synthesised and developed by the CPG Development team has been used. Please use this guidance alongside all professional standards and clinical guidelines relevant to your profession and your place of work.

A Quick Reference Guide to the CPGs is provided as part of this Executive Summary.

Table 1: Clinical Practice Guideline Recommendations: Quick Reference Guide

1	Referral for FES
1.1	Anyone with an upper motor neurone condition should be eligible for evaluation of possible benefit from FES and eligible for receiving FES, rather than eligibility being determined by which health condition they have.
1.2	People should be referred for FES if they have an upper motor neurone lesion, have enough passive movement at their ankle (i.e. another person can move their foot) to make walking with FES possible and one of the following apply: • They find it hard to control movement of their lower limb joints when walking (possibly only when tired or doing something else at the same time) • They have difficulty keeping their balance when walking (possibly only when tired or doing something else at the same time) • They cannot or will not use a splint (ankle foot orthosis or knee ankle foot orthosis) for some reason
1.3	People with Motor Neurone Disease, Polio, Guillain-Barre Disease, and Peripheral Nerve Damage do not generally benefit from FES except where they have some function in the nerves of their legs.
1.4	Only people who can fit the device each day themselves or have assistance from another person on a regular basis who can fit the device, should be referred for FES.
1.5	Only people who can attend for follow-up sessions to check on their progress should be referred for FES.

2	Potential benefits of using FES
2.1	When talking to people about whether FES may be of benefit to them, it is important to discuss the possible positive impacts in the context of their personal goals.
2.2	Once a person is medically stable, FES may be useful in supporting early rehabilitation goals that relate to mobility, by moving the joints and stimulating the sensory and motor systems.

2.3	People may find FES useful to support them when their needs have progressed, for example, to walk short distances and to help them transfer e.g. from wheelchair to bed and back.
2.4	When talking to people about whether FES may be of benefit to them, it is important to be clear about what to expect if they have a health condition that is stable (e.g. stroke) or progressive (e.g. Multiple Sclerosis).
2.5	FES may improve people's walking in different ways, such as being able to walk faster or further, on different surfaces more safely, with fewer trips or falls, and feeling more confident and like it takes less effort.
2.6	Some people with a stable/non-degenerative condition may experience a therapeutic effect on walking speed which is more likely if used as part of a more intensive rehabilitation programme (Note: in this context therapeutic effect means that when a person is walking without their FES on they still experience increased walking speed that continues over time).
2.7	FES may make it easier for people to look after themselves and take part in different types of activity.
2.8	In comparison with non-customised orthotics, some FES devices may be less visible under clothes and may give greater choice of footwear.
2.9	FES may increase quality of life, for example, through increasing feelings of self-esteem, capability, wellbeing and participation in life.
2.10	FES may help to strengthen people's muscles.
2.11	FES may reduce stiffness in people's muscles and joints while using FES.
2.12	FES may help people become fitter.
2.13	Once a person is wearing FES, it may make it easier for them to do some things more independently.

3	Considerations and precautions when using FES
3.1	When talking to people about whether FES may be of benefit to them, it is important to put this in the context of the commitment needed in making sure it is set up as well as possible for them, learning to use it, and strengthening the stimulated muscles, which may take time and require repeat appointments.
3.2	When talking to people about whether FES may be of benefit to them, it is important to clarify whether they are using it as a short-term rehabilitation tool, or to support their walking daily for the foreseeable future.
3.3	Where people will find it difficult to engage with the process of learning and problem-solving in relation to FES use, assessment for FES to support walking must include discussion of how this will be supported.
3.4	If FES is being used to support walking and a person is not able to stand up from sitting independently, the assessment must include discussion of how this will be managed.

3.5	Severe joint stiffness or fixed contractures at the ankle can be a reason not to use FES with a person.
3.6	Poor skin condition or skin lesions where electrodes are placed are reasons not to use FES with a person.
3.7	If a person has known history of cancer in the region where FES will be applied discussion of the relative risks and benefits would be required.
3.8	If a person has a known health condition relating to their heart or blood pressure discussion of the relative risks and benefits of using FES would be required, as for any new exercise intervention.
3.9	A person with a pacemaker should consult a cardiologist to get clearance to use FES.
3.10	Due to the lack of evidence which supports the safe use of FES during pregnancy, discussion of the relative risks and benefits would be required.
3.11	It is important for people who provide FES to be aware of Autonomic Dysreflexia (increased blood pressure and very low heart rate) and its management, to make sure that this is considered where appropriate in assessment and monitoring of people using FES.
3.12	When talking to people about whether FES may be of benefit to them, it is important to discuss the possible negative impacts/ adverse events.
3.13	Some people find that when they start to use FES it can be uncomfortable and difficult to use.
3.14	FES can affect muscle spasm and/or spasticity in different ways and it is important to discuss this with people who may be affected.
3.15	FES can affect pain in the muscles or joints during walking in different ways and it is important to discuss this with people who may be affected.
3.16	Some people experience skin irritation under FES electrode pads and may need to use strategies to minimise this.
3.17	If a person develops recurrent adverse events (negative impacts), FES use should be stopped.
3.18	If a person develops any of the listed reasons for not using FES, its use should be stopped while the reason persists.

4	Access to FES services
4.1	FES service provision should ensure that people who have the ability to refer to a FES service are aware of the service and have the referral criteria.
4.2	FES service provision should promote their service more publicly using different media so that people who may benefit from FES are aware of it.
4.3	FES services should provide information on how people can seek funding of FES if this is not available through the service.

5	FES service provision
5.1	FES service provision (funding and referral criteria) should not vary between people with different health conditions unless the health condition is a reason not to use FES.
5.2	FES service provision should consider the whole person and all their needs, rather than only the function of walking.
5.3	FES services should include conversations with the person about what they hope to gain from using FES and how to support them in overcoming possible barriers to learning and continuing to use FES over time.
5.4	FES service provision should consider a person's physical impairments and functional deficits and include appropriate strategies to support them.
5.5	FES service provision should consider how FES can support a person in their activities of daily living and include strategies to support their capabilities in these.
5.6	FES service provision should consider whether there are other ways in which physiotherapy and other services may benefit the person and whether this can be delivered within the service or a referral can be made to another service, for example, gait training.
5.7	FES service provision should consider including mechanisms to enable peer support in using FES.
5.8	FES service provision should include appropriate risk assessment and strategies/ policies to reduce risks that have been identified, for example, in relation to a person's understanding of how/what/when to use FES.
5.9	FES service organisations should include financial planning to ensure an appropriate supply of FES devices and consumables as well as maintenance contracts to support existing and new FES users.
5.10	FES service organisations should consider sustainability through recycling of FES devices where fit for purpose.
5.11	A FES service organisation should include administrative support to enable responsiveness to patient needs.
5.12	Guidance should be provided to people who use FES for what to do if they experience difficulties when the service is not open (for example, at the weekend).

6	Initial assessment and treatment
6.1	The initial assessment should consider the possible alternative devices available (e.g. ankle foot orthoses) and positive and negative aspects of each.
6.2	The initial assessment should evaluate whether a person is able to understand how to use FES or lives with someone who can help.
6.3	During the initial assessment the therapist should find out whether it is possible to use electrical stimulation to lift the foot into a right-

	angle position (dorsiflexion) with the outside 'edge' of the foot slightly higher than the inside (eversion), or to help bend the knee.
6.4	During the initial assessment the therapist should find out whether the person requires support to put the device on and whether this is available.
6.5	During the initial assessment and subsequent appointments the therapist should find out whether the person can tolerate / accept the sensation of electrical stimulation.
6.6	During the initial assessment and subsequent sessions the therapist should explore what the person hopes to gain from using FES and how to support them in overcoming possible barriers to learning and continuing to use FES over time.
6.7	During the initial session the FES provider should educate the FES user on strategies to ensure safe use.
6.8	During the initial session the FES provider should inform the FES user that FES devices are individualised to the person and should not be shared with other people.
6.9	The FES providers should conduct a holistic assessment of the person to explore their broader health and wellbeing needs.
6.10	In the initial session or subsequent session the FES provider should work with the FES user to optimise the settings of the device for that person and practise its use.
6.11	In the same session or subsequent session the FES provider/ service should provide training on how to use FES in daily life.
6.12	In the initial session, or a subsequent session, FES services should ensure that people know how to access ongoing support and when to do so.
6.13	FES services should ensure that any person who is involved with the FES user (e.g. carer, guardian) is included where appropriate, in line with the preferences of the FES user.
6.14	FES services should ensure that FES users have received sufficient assessment, training and education to ensure that they are competent in using the FES device before being given the device to use independently.

7	Monitoring and ongoing support
7.1	FES services should carry out in-person/telephone/online follow-up session with FES users within the first six weeks of use and on a planned basis for as long as the device is used.
7.2	During the in-person/telephone/online follow-up sessions the therapist should explore whether the person is safe when using FES and is not experiencing negative effect.
7.3	During in-person/telephone/online follow-up sessions the therapist should explore whether any further adjustments are needed to the FES device to enable the person to manage better and/or more safely and/or comfortably.
7.4	During the in-person/telephone/online follow-up sessions the therapist should explore whether the person is experiencing falls or fear of falling.

7.5	During the in-person/telephone/online follow-up sessions the therapist should explore any changes in walking and balance related measurement.
7.6	During in-person/telephone/online follow-up sessions the therapist should explore any changes in lower extremity motor function, for example, due to a new health condition.
7.7	During the in-person/telephone/online follow-up sessions the therapist should explore any changes in walking distances in the community.
7.8	During in-person/telephone/online follow-up sessions the therapist should explore progress towards the person's personal goals.
7.9	During in-person/telephone/online follow-up sessions the therapist should explore impacts on the person in relation to their activities of daily living, life roles and quality of life.
7.10	FES services should provide ongoing telephone/online and technical support for FES users while they are still using the device.

8	Minimum training for FES providers
8.1	FES providers should receive at least one day of initial training in using the specific FES device that they wish to work with.
8.2	People who have not completed a device-specific training course should not be able to provide FES devices for the purpose of supporting a person's walking.
8.3	FES providers should be clinicians with appropriate healthcare training, knowledge and experience in relation to the health condition underlying the need for FES, and training in FES provision, or working under the supervision of such clinicians.
8.4	FES providers should take professional responsibility for undertaking appropriate continuing professional development relating to FES provision to maintain their competencies.
8.5	FES providers should maintain their practice in relation to FES provision and be able to demonstrate that they are using their skills regularly.

3. Introduction

The Association for Chartered Physiotherapists in Neurology (ACPIN) is a dynamic and proactive charity and one of the largest Professional Networks recognised by the Chartered Society of Physiotherapy. As both a professional network and a charity, it is concerned with all aspects of physiotherapy relating to the needs of neurologically impaired adults and their relatives and carers.

ACPIN's drive is to facilitate research in neurophysiotherapy that leads to best practice, encouraging the pursuit of excellence in the field of neurological physiotherapy practice. ACPIN recognises that best practice is created through strong robust research and clinical guidelines developed from research.

ACPIN recognised that to lead and champion best practice, a clinical practice guideline based on the best available evidence was needed. At the 2016/2017 ACPIN conference we scoped attendees to determine if this was a good direction and were met with an overwhelmingly positive response. We discussed this with the ACPIN president Professor Jane Burridge and identified that a working group was needed to take this work forward.

This led to a collaboration with Queen Margaret University (QMU) (2021), whose aim is to: "shape a better world through education, research and innovation. In doing so, we enable individuals and communities to flourish". ACPIN and QMU emphasise person-centred practice and cultures, with a focus on respect for the values and dignity of all those people involved in healthcare interactions (McCormack et al., 2021). This has led to the CPG development team taking great care to ensure appropriate involvement of people with lived experience throughout. QMU is also involved in work to decolonise research and value different ways of knowing (Hammond, 2018), which is reflected in the value placed on different types of evidence within the CPG development process.

This guideline has been produced to inform all stakeholders involved with FES. We include the following stakeholders, referred to throughout this document as:

- FES users: people who use FES for mobility;
- FES providers: people who work with people to assess and manage their mobility using FES;
- FES service leads: people who have a strategic and/or leadership role in delivery of FES services;
- FES developers: people who have a role in the development of FES devices;
- FES researchers: people who carry out research relating to FES; and

- FES distributors: people who distribute FES devices for use by FES providers and/or FES users.

Early in the project we consulted stakeholders about how they might use such a document, and their priorities have informed our aims (Bulley, Meagher et al., 2021). Consequently, this CPG aims to:

- enable people to advocate for funding of appropriate FES service provision locally in a way that is holistic and sustainable and does not discriminate in relation to access;
- ensure that FES services and referral criteria are known and used by health professionals at appropriate points in the person's healthcare journey;
- support design and development of FES services using best evidence to provide a rigorous pathway of care with appropriate and non-discriminatory referral criteria, assessment, education and monitoring mechanisms;
- ensure that FES users can access support to use FES effectively and in the long-term where appropriate;
- enable FES providers to gain training, build their experience and access to peer support to optimise their practice in providing FES; and
- improve the experience of FES users and enable optimal participation in life.

By synthesising published evidence with expert consensus where necessary the recommendations within this guideline should assist clinical decision making in collaboration with the potential/actual FES user, with full consideration of their views and preferences.

In order to develop the Clinical Practice Guidelines using person-centred principles, a multi-staged process was followed:

1. First, work was carried out to find out what people with different experiences of FES thought about the need for a CPG and what it should address. It was clear that people felt this was important and they provided insights into important areas of content and expectations of practice in relation to FES when used to support mobility for people with upper motor neurone lesions.
2. At the same time, an overview of systematic reviews was conducted to find out the status of evidence in relation to the use of FES to support walking in people with a UMN lesion. Existing systematic reviews were rigorously appraised. Systematic reviews are research studies that use a rigorous method to search for and synthesise specific types of relevant research study to come to conclusions about whether something works – in this case, FES. The overview only included systematic reviews that investigated walking as an outcome of using FES. The reviewers also examined these systematic reviews for information regarding impacts of FES on balance, quality of life, walking-related activities of daily living, independence, falls and spasticity, as well as safety and adverse effects. Systematic reviews that reported on the effect of FES on the walking of people with Stroke, Parkinson's Disease (PD), Multiple Sclerosis (MS), Incomplete Spinal Cord Injury (SCI), Traumatic Brain Injury (TBI) and adults with Cerebral Palsy (CP) were eligible for inclusion in the overview. Only systematic reviews focussing on stroke survivors, people with MS and SCI were located, however.

3. In a), people identified the need for guidelines on specific aspects of service delivery that were not addressed in the current evidence appraised in b). This necessitated further collection of information using a Delphi consensus method, to ensure recommendations are in line with current thinking about optimal clinical practice from people with appropriate experience and expertise.
4. The results of the first three stages enabled conclusions about what FES service provision should look like when supporting mobility for people with upper motor neurone lesions, provided in this CPG document.

This document directs the reader to published detail regarding the methods and results for each stage, as well as the manner in which these were synthesised. A Quick Reference Guide is included with the Executive Summary to support practice. An implementation plan is under development, informed by stakeholder consultation. This may include production of audit tools to support service improvement and guidelines for people in practice to develop their capabilities in providing FES. Regular update of the CPGs in response to new evidence is also planned.

When considering the trustworthiness of CPGs, it is important to consider the credentials and any conflicts of interest of the people most involved – the CPG Working Group, who were involved in stages a) to d) and the Delphi Study Steering Group, some of whom were most involved in stages c) and d). The development, research, distribution and provision of FES relies on a multidisciplinary team with different expertise. For this reason, the Working Group included a person with lived experience of using FES, members of the UK Chartered Society of Physiotherapy with State Registration (Health and Care Professions Council) with representatives of ACPIN, people who have strategic oversight of FES services, and people who distribute, design and research FES internationally. Their credentials are listed in Appendix 1. The Delphi Steering Group included the Working Group and health professionals who practice internationally using different types of FES.

It is important to note that different commercial FES devices are used internationally, developed by different companies. Most stakeholders have different experience and affiliations relating to these. From the start of the CPG development process this presented a possible conflict of interest and barrier to progression. For this reason an academic with research experience relating to FES, but with no affiliation to any specific FES provider, was invited to take a leading role in the development process and took an impartial and inclusive approach to CPG development. Conflicts of interest of the CPG development team are openly acknowledged in Appendix 1. These were carefully managed to ensure that the final document would be trustworthy. The guideline development process was supported by the Chartered Society of Physiotherapy Professional Network Fund and ACPIN funding. No funding was received from any company or organisation involved in the development, distribution or provision of FES.

It is important to note that this CPG is not a legally binding document. The best evidence that could be synthesised and developed by the CPG Development team has been used. Please use this guidance alongside all professional standards and clinical guidelines relevant to your profession and your place of work.

3.2 Clinical Practice Guidelines

CPGs usually provide statements relating to specific healthcare contexts in relation to what works best, for whom, and how. This can support decision making by people seeking care or support, people providing it, and people funding it. Ideally, this would lead to greater equity of healthcare and prevent both mistakes and waste (Kredo et al 2016). Definitions of CPGs vary, with early emphasis on the need for guidelines to be systematically developed [Institute of Medicine 1990]. Over time there has been increasing priority given to use of rigorous methodologies in their development, with assessment of benefit and risk. CPGs are expected to be based on the best available evidence [Institute of Medicine 2011].

It is important to briefly explore the meaning of 'evidence' as it is used within this CPG document. Evidence is often seen as peer-reviewed research articles that report studies carried out using specific methodologies. Critical appraisal processes are used to give verdicts on how trustworthy these studies are, with greater credibility attributed to specific study designs, such as a Randomised Controlled Trial. The foundations of this lie in the Evidence Based Medicine / Practice paradigm, which emphasises the interaction between patient preference, clinical expertise, and best available evidence (Haynes et al., 1996). Best available evidence is usually determined using the 'pyramid of evidence' which places quantitative study designs higher than qualitative (Guyatt et al., 2008). Amongst quantitative study designs there is more faith in study designs that are believed to determine cause and effect – the Randomised Controlled Trial and studies that synthesise these e.g. systematic reviews and meta-analyses (Cowen et al., 2017). There is critique of the over-reliance on the 'pyramid of evidence' which is seen to be reductionist (Greenhalgh et al., 2014). It is described as failing to capture 'the context, complexity, and patient centeredness that characterize expertise in physiotherapy practice' (Shaw et al., 2010, p. 514). Despite this, the pyramid of evidence is frequently given priority over patient preference and clinical expertise within the Evidence Based Practice Paradigm, for example, when grading the trustworthiness of recommendations within CPGs (Reivonen et al 2021).

We are in a time of rapid change in relation to the way in which evidence is viewed.

The priority placed on person-centred practice is appropriately filtering from the World Health Organization through national bodies (WHO, 2016; McCormack et al., 2021). Person-centredness has emerged from certain ways of looking at the world that contrast dramatically with the philosophical roots of the evidence-based pyramid. The latter is based in positivism – where specific quantitative methods are used to develop knowledge and trustworthiness of that knowledge is judged in specific ways (e.g. whether there was a control group). Positivism is philosophically consistent with the biomedical model of health, rather than more biopsychosocial or person-centred approaches which are now healthcare priorities (Shaw et al., 2010). Shaw et al (2016) emphasise that the World Confederation of Physical Therapy recognise and engage in the debate regarding definitions of best practice. This debate is further reinforced by the global movement to decolonise research and curricula. Whilst it is in its early stages for many professions and disciplines this must be considered where we are striving for inclusivity. Amongst many other implications

of decolonising research, one is that we must give full credibility to different ways of knowing (Ndege and Onyango, 2021).

Our CPG development process aimed to respect these different priorities. We used the philosophical approach of Pragmatism (Shaw et al., 2016), where focus is on the problem and the solution. We took the view that ‘‘truth is synonymous with the solution to a problem’’ (Mead, 1964, p. 328, in Shaw et al., 2016). In line with this paradigm, we used multiple methods that were most appropriate to the question(s) to find a more comprehensive answer and develop practical recommendations. This approach has affected our preferred CPG definition from Treweek et al (2013): “Guidelines are a convenient way of packaging evidence and presenting recommendations to healthcare decision makers”. We emphasise that evidence of different types is appraised within their context and given equal priority within this process, in line with changing notions of evidence based practice (Reivonen et al 2021).

There is no one way of developing a CPG, however, Kredo et al. (2016, p123) state that “transparently constructed evidence-informed approaches integrated with expert opinion and patient values have rapidly gained acceptance over the past two decades as the best approach to CPG development.” It is also crucial to recognise that CPGs provide information to be used within the specific interaction with a person seeking care or support. Much guidance required to guide optimal service provision is not derived from randomised controlled trials and other types of evidence are more appropriate. This includes insights into people’s preferences and service contexts (Reivonen et al., 2021]. We explain each step taken in the development of this CPG within the Methods and explain where we have synthesised the evidence in a manner that aims to honour the philosophies involved in decolonising research and person-centred practice.

3.3 The need for guidelines specific to Functional Electrical Stimulation to Support Mobility

Health conditions that involve upper motor neurone lesions often cause leg weakness or paralysis. Examples include Stroke, Multiple Sclerosis, Cerebral Palsy and Spinal Cord Injury. This weakness affects mobility, for example, by making it hard to lift the foot when walking, increasing risks of tripping, falling and fatigue. This can then affect people’s ability to participate in life activities and roles, impacting negatively on their overall wellbeing.

There are different strategies to help people with their mobility. One is called Functional Electrical Stimulation (FES) which is an assistive technology that stimulates muscles in the leg that helps that person to achieve greater mobility. For example, for people who find it hard to lift their toes when swinging their leg through during walking, FES may help to stimulate this action. FES was developed as a research tool and over the last 15 years it has become widely used in clinical practice

in around 70 countries and with 8,000-10,000 people in the UK (Impact case studies Research Excellence Framework, 2014). It has been recommended by the National Institute for Health and Care Excellence in their clinical guidelines (NICE, 2009). These guidelines are valuable in that they state: “current evidence on the safety and efficacy (in terms of improving gait) of FES for drop foot of central neurological origin appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit” (NICE, 2009; p 2). They emphasise that a rehabilitation multidisciplinary team should be involved in selecting people who can benefit from using FES. They provide some detail on who can benefit from FES and on the procedure, its efficacy and safety. The NICE guidelines do not contain the detail that would enable providers to know how best to design and evaluate a safe and effective service that provides FES to people with mobility difficulties due to upper motor neurone lesions. There is a need for trustworthy guidance that focuses on key issues, including: how FES helps patients; who should be referred for FES; how people should be assessed and treated; and how people should be supported and monitored over time.

There is variation within the UK and internationally in relation to the availability and design of FES services. Often people only have the option of ankle foot orthoses through their local National Health Service provision. This is appropriate for some people but others find it causes discomfort and skin problems (Bulley et al 2011; 2015). Not everyone with mobility difficulties due to an upper motor neurone lesion will benefit from FES for different reasons. It is important however that everyone has the opportunity for referral and assessment to explore its potential for use in their lives.

4. Methods used to develop the Clinical Practice Guideline

4.1Selecting the focus of the CPG

When developing this CPG, attention was paid to specific guideline development methods, such as that described by the National Institute for Health and Care Excellence (NICE, 2014). Key differences in the process are identified below with reasons given. First, this CPG was prompted by a specific need that was identified through conversations with people who use FES and people who provide FES, drawn together by ACPIN. This contrasts with the process of referring a topic to NICE who then make decisions about which will lead to guideline development. In order to take on this substantial task of developing a CPG, a Working Group was formed (see Appendix 1). As previously explained, this group was formed with clear priority on ensuring that different stakeholders were represented and potential conflicts of interest were managed.

4.2 Determining the scope of the CPG

Once a topic has been selected by NICE for guideline development, the developer drafts the scope of the guideline and seeks stakeholder feedback. This was reversed for our CPG development process which followed a person-centred approach by first exploring what is meaningful to the people most affected (Bulley et al., 2021). This involved a multi-method exploration of stakeholder views on the need for a CPG and on what its scope should be (Bulley, Smith et al., 2021). You can find the full explanation of methods and results in an open access publication at this link: https://bmcneurol.biomedcentral.com/articles/10.1186/s12883-021-02299-1 (Bulley, Meagher et al., 2021). An important point to note is that throughout this process, the scope altered over time from a focus on foot-drop, to walking, and finally to a wider focus on use of FES to optimise mobility.

It is important to consider the trustworthiness of this process, addressed in greater detail by Bulley, Meagher et al. (2021). Our exploration of stakeholder views aimed to triangulate insights from the views of different stakeholders, using different methods. We carried out a pragmatic online survey of 223 people through the email distribution list of ACPIN, which obtained a breadth of views of physiotherapists in particular. At the same time, we designed a qualitative service evaluation and patient public involvement consultation to gain greater depth of insight from a wider variety of stakeholders. This included six people who use FES, three family and carers of people who use FES, four people involved in delivering a physiotherapy FES service, two people with strategic oversight over two different FES services, one of whom was also a FES developer and researcher, one other FES researcher, and one person with experience of distributing different types of FES. Established and rigorous qualitative methods were used, and analysis was carried out by experienced researchers who did not have a conflict of interest. Most (although not all) of the qualitative interviews were with people associated with two established FES services

and more participants in the survey and the qualitative consultation were based in England, demonstrating a lack of geographical diversity. This reflects the unequal access to FES services across the UK.

4.3 Evidence Review

The next stages of NICE guideline development involve design of a structured review of the evidence with call for specific expert testimony where needed. The Clinical Guideline Working Group decided to conduct an overview of existing systematic reviews of the literature, rather than a single systematic review. This was due to the number of systematic reviews existing already, and the wide scope of this CPG which addresses the needs of people with different upper motor neurone lesions. The specific clinical question addressed was: "Is functional electrical stimulation effective for improving walking characteristics in adults with lower limb weakness due to an upper motor neuron lesion?" Our evidence synthesis process was a systematic review of systematic reviews which is described in the published protocol, found at this link:

https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=150899

(Busselli et al., 2019). You can find the full account as an open access publication at the following link: https://onlinelibrary.wiley.com/doi/epdf/10.1111/aor.14563

The Overview of Systematic Reviews led to valuable conclusions. The majority of individual research studies and systematic reviews have focused on FES use by people who have had a stroke (16 reviews including 154 studies). Five systematic reviews included people who had spinal cord injuries, (69 studies), while two systematic reviews included people living with MS (32 studies). We assessed the quality of the review methodology using the AMSTAR2 (Shea et al., 2017). Nine systematic reviews focusing on people after stroke included meta-analysis and the quality of the evidence presented in these studies was evaluated using the GRADE approach (Guyatt et al., 2011). Methodological quality of the reviews ranged from critically low to high and quality of the evidence ranged from very low to moderate, most often due to small numbers of study participants and lack of blinding. The majority of the systematic reviews focused on differences in walking speed, while a small number reported on balance and activities of daily living and only one summarised the evidence on falls and adverse effects.

The Evidence Synthesis study showed that there is evidence of benefits to walking speed from use of FES when compared with no FES. In the studies with people post-stroke there was also evidence of a training effect, i.e. unassisted walking at follow-up is improved compared to walking at baseline. The reviews also concluded that FES is not better or worse compared to using an Ankle Foot Orthosis for people with foot-drop after a stroke in relation to walking speed, falls or adverse effects. The same is the case for falls and adverse effects. The Evidence Synthesis was conducted with careful attention to strategies that increased its trustworthiness, following PRISMA guidelines throughout (PRISMA, 2021).

4.4 Development of CPG Statements

In a NICE guideline development journey (NICE, 2014) the evidence synthesis and expert testimony are used to develop draft recommendations which are then subjected to stakeholder consultation and revision. Due to the study designs synthesised within our evidence synthesis, however, there were still many questions about issues that stakeholders wished to be addressed within the CPG. Continuing our focus on equally prioritising other forms of evidence we used our analysis from the stakeholder consultation process to develop initial statements relating to optimal practice relating to different aspects of the journey through a FES service. These initial statements were then used in a Delphi Consensus Study. We continued our person-centred approach by ensuring that our Delphi Expert Panel, who reviewed the statements, included substantial representation from people with lived experience of using FES (19 people out of 65 respondents to the first survey – 29%). This is explained fully in an open access publication, available at the following link: https://onlinelibrary.wiley.com/doi/epdf/10.1111/aor.14611

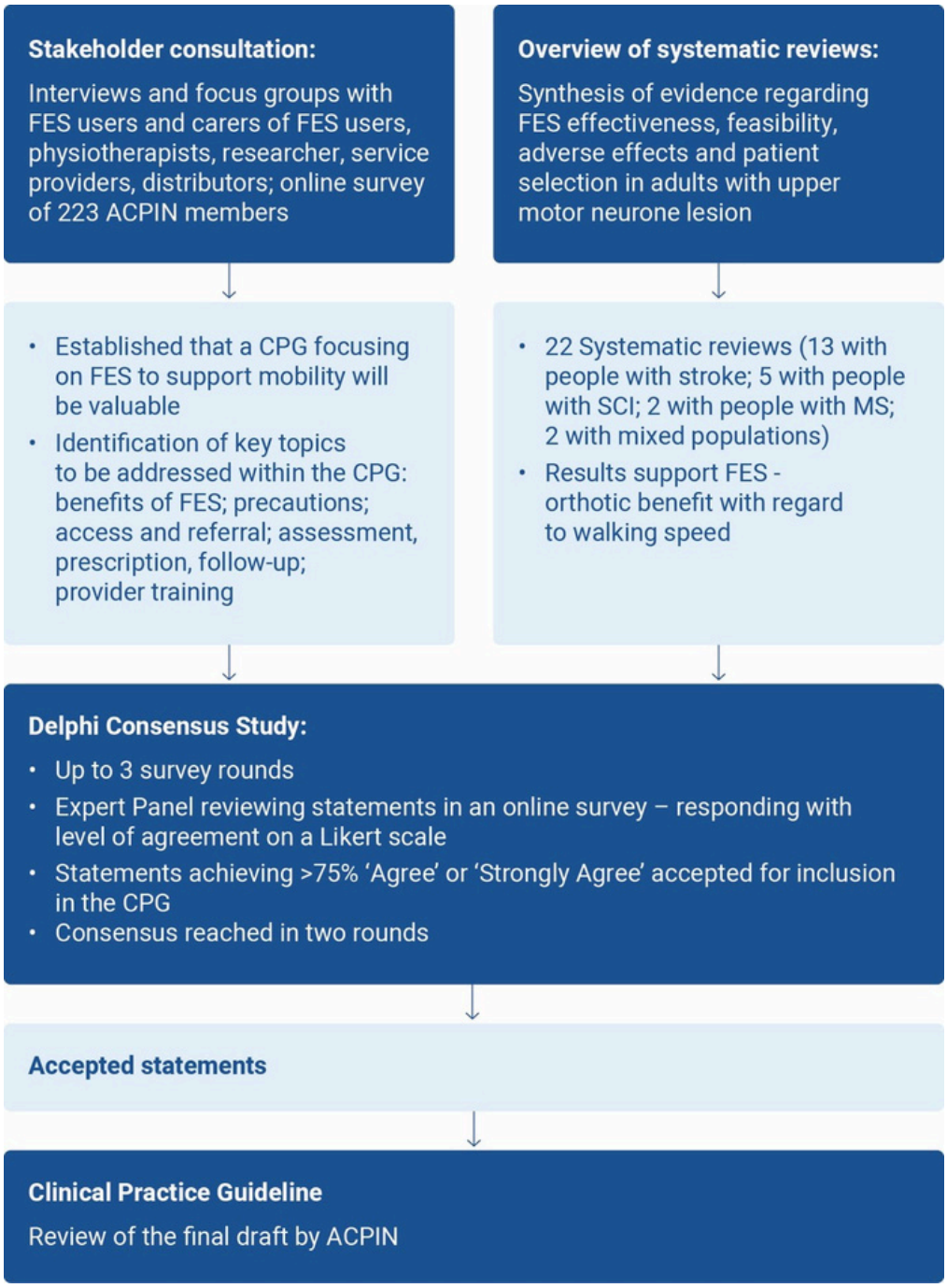
We used different strategies to increase the rigour of our modified online Delphi Consensus Study, including involvement of people who represent different forms of appropriate experience and expertise. When designing a Delphi Study the aim is to write statements relating to best practice, test these through a survey with the Expert Panel, and accept any that reach a specific level of consensus. In our study this was set at: over 75% of respondents selecting 'Agree' or 'Strongly agree' on the Likert Scale relating to the statement. Those statements that do not reach consensus are revised based on open response comments from the Expert Panel and discussion within the Delphi Study Steering Group. A specific limit is placed on the number of survey rounds and all statements that have reached consensus by the end of this process are accepted. We selected three survey rounds as our limit and found that we reached consensus within two rounds. This may be due to the rigorous stakeholder consultation process that informed the first stage and supports the credibility of the findings. Further strategies to increase rigour were used, including clear inclusion criteria, auditable decision-making, mechanisms to reduce bias in analysis, and anonymity within expert panel feedback (van der Linde et al., 2005).

4.5 CPG Review and Endorsement

The final stages of NICE guideline development involve review by NICE for quality assurance purposes. In the context of this CPG, the ACPIN Committee took responsibility for reviewing the final draft of the document. A next stage is to send this for review by the International FES Society to establish whether they are willing to endorse this document in relation to its quality and international relevance.

Steps identified in the development of the guideline are summarised in Figure 1.

Figure 1. Summary of the Clinical Practice Guideline Development Process


Stakeholder consultation:
Interviews and focus groups with FES users and carers of FES users, physiotherapists, researcher, service providers, distributors; online survey of 223 ACPIN members
Overview of systematic reviews:
Synthesis of evidence regarding FES effectiveness, feasibility, adverse effects and patient selection in adults with upper motor neurone lesion
• Established that a CPG focusing on FES to support mobility will be valuable
• Identification of key topics to be addressed within the CPG: benefits of FES; precautions; access and referral; assessment, prescription, follow-up; provider training
• 22 Systematic reviews (13 with people with stroke; 5 with people with SCI; 2 with people with MS; 2 with mixed populations)
• Results support FES - orthotic benefit with regard to walking speed
Delphi Consensus Study:
• Up to 3 survey rounds
• Expert Panel reviewing statements in an online survey – responding with level of agreement on a Likert scale
• Statements achieving >75% 'Agree' or 'Strongly Agree' accepted for inclusion in the CPG
• Consensus reached in two rounds
Accepted statements
Clinical Practice Guideline
Review of the final draft by ACPIN

5. Clinical Practice Guideline Statements

This rigorous development process has led to specific statements that are applicable to all adults with lower limb impairment due to upper motor neuron lesion, regardless of the underlying aetiology.

They relate to the decision-making process in relation to whether and when a person might benefit from FES, throughout the journey of access, assessment, ongoing follow-up and monitoring, and provider training. There is no clear 'discharge point' for FES users and this guideline makes recommendations relating to long-term support. The guidelines relate to adults with upper motor neurone lesions, including the following: Stroke; Parkinson's; Multiple Sclerosis; Incomplete Spinal Cord Injury; Traumatic Brain Injury; and Cerebral Palsy. The guidelines address the following areas:

1. Referral for FES
2. Potential benefits of using FES
3. Considerations and precautions when using FES
4. Access to FES services
5. FES service provision
6. Initial assessment and treatment
7. Monitoring and ongoing support
8. Minimum training for FES providers

There is an explanation in each section which indicates the forms of evidence used to produce the recommendations and our evaluation of how appropriate this form of evidence is for the context of the recommendations.

1 Referral for FES

The NICE Clinical Guidelines state that "Functional electrical stimulation is used to treat the effects of upper motor neurone lesions that can result from conditions such as stroke, cerebral palsy, multiple sclerosis or spinal cord injury but may occur in other conditions. Symptoms and signs of upper motor neurone lesions include muscle weakness in a pyramidal distribution (an imbalance causing arm flexion and leg extension), hypertonicity, exaggerated reflexes, clonus and an extensor plantar response. Functional electrical stimulation is not normally suitable for patients with lower motor neurone lesions" (NICE, 2009 p. 2). The Evidence Synthesis provided an updated overview of the evidence, supporting that people with several different upper motor neurone conditions have potential to benefit from FES, with stronger evidence relating to increased walking speed as an impact. The search strategy did not locate any systematic reviews focusing on people with Parkinson's, Traumatic

Brain Injury, or adults with Cerebral Palsy and it would be valuable for future research to address this gap.

It was clear from the initial Stakeholder Consultation that participants felt strongly that information should be included in the CPG regarding who is most likely to benefit from FES. Participants felt that it was important that the CPG did not differentiate between different upper motor neurone conditions, instead recommending that anyone with potential to benefit is able to receive a referral and assessment. One Delphi Panellist who uses FES described the current situation as discriminatory on the basis of which health condition you are living with. Many participants in the Stakeholder Consultation and in the Delphi Study believed that people with appropriate neural function should have the opportunity to be assessed for FES and that the influences on whether or not a person can use it related to other factors such as their social support and access to services for follow-up support.

Throughout the CPG development process it became clearer that FES is used to support mobility in different ways – from early rehabilitation and transfers to walking – and criteria for referral reflect this. Further research focusing on use of FES in early rehabilitation to support mobility would be valuable.

The triangulation of evidence from an established clinical guideline (NICE, 2009), our updated Evidence Synthesis, published Stakeholder Consultation, and Delphi Consensus Study provides substantial evidence for the statements below.

1.1	Anyone with an upper motor neurone condition should be eligible for evaluation of possible benefit from FES and eligible for receiving FES, rather than eligibility being determined by which health condition they have.
1.2	People should be referred for FES if they have an upper motor neurone lesion, have enough passive movement at their ankle (i.e. another person can move their foot) to make walking with FES possible and one of the following apply: They find it hard to control movement of their lower limb joints when walking (possibly only when tired or doing something else at the same time) They have difficulty keeping their balance when walking (possibly only when tired or doing something else at the same time) They cannot or will not use a splint (ankle foot orthosis or knee ankle foot orthosis) for some reason
1.3	People with Motor Neurone Disease, Polio, Guillain-Barre Disease, and Peripheral Nerve Damage do not generally benefit from FES except where they have some function in the nerves of their legs.
1.4	Only people who can fit the device each day themselves or have assistance from another person on a regular basis who can fit the device, should be referred for FES.
1.5	Only people who can attend for follow-up sessions to check on their progress should be referred for FES.

2 Potential benefits of using FES

The Stakeholder Consultation showed clear evidence that people believed current research evidence and consensus relating to impacts of FES should be included in the CPG. The Evidence Synthesis focused particularly on walking and demonstrated evidence of increased walking speed. This study as well as the Stakeholder Consultation and Delphi Study provided evidence that triangulated consistently in relation to the orthotic effect of FES being clearer than therapeutic effects. In other words – there is substantial evidence that FES improves aspects of walking (particularly speed) when people are wearing FES. When they remove it, some people may experience ongoing benefits but this is less certain. It is important to remember that people do not just make decisions based on their walking speed, however, therefore further insights are needed in relation to people's views and experiences.

As explained more fully by Bulley et al (2021), people described life-changing impacts of using FES which include the range of impacts contained within this section of CPG statements. One Delphi Panellist stated that FES had liberated them. These findings triangulate with comments made in the Delphi Study. One service provider indicated that FES has a very positive financial impact on the NHS through falls reduction and this would be a useful avenue for future research. There is evidence from the Stakeholder Consultation, the Evidence Synthesis and the Delphi Study that the impacts are individual and may be influenced by the nature of the person's health condition, for example, whether this is progressive or not. This highlighted the need for FES use to be carefully considered in relation to each person and their goals. It also became apparent through the CPG development process that people use FES to stimulate mobility in different ways over the rehabilitation journey, for example, by increasing passive range of movement, stimulating neuroplasticity, increasing sensory input, and muscle strengthening. The Stakeholder Consultation also highlighted that FES is not an intervention to be used in isolation; people may need to build their strength in order to use it optimally. A person with lived experience in the Delphi study explained that they use FES in its exercise mode to stretch or activate muscle activation before walking. Other Delphi Expert Panellists described using FES for transfers only, or for walking very short distances that increase independence e.g. in using the toilet. One person explained that this is valuable to people's dignity. It was also clarified in the Delphi study that while FES may support a person to be more independent once they have put it on, this process each day is not straightforward and may rely on another person. The Stakeholder Consultation and Delphi study provided evidence that FES use can have substantial positive psychological impacts on wellbeing, confidence, self-belief, self-esteem, and ability to participate in life.

2.1	When talking to people about whether FES may be of benefit to them, it is important to discuss the possible positive impacts in the context of their personal goals.
2.2	Once a person is medically stable, FES may be useful in supporting early rehabilitation goals that relate to mobility, by moving the joints and stimulating the sensory and motor systems.
2.3	People may find FES useful to support them when their needs have progressed, for example, to walk short distances and to help them transfer e.g. from wheelchair to bed and back.

2.4	When talking to people about whether FES may be of benefit to them, it is important to be clear about what to expect if they have a health condition that is stable (e.g. stroke) or progressive (e.g. Multiple Sclerosis).
2.5	FES may improve people's walking in different ways, such as being able to walk faster or further, on different surfaces more safely, with fewer trips or falls, and feeling more confident and like it takes less effort.
2.6	Some people with a stable/non-degenerative condition may experience a therapeutic effect on walking speed which is more likely if used as part of a more intensive rehabilitation programme (Note: in this context therapeutic effect means that when a person is walking without their FES on they still experience increased walking speed that continues over time).
2.7	FES may make it easier for people to look after themselves and take part in different types of activity.
2.8	In comparison with non-customised orthotics, some FES devices may be less visible under clothes and may give greater choice of footwear.
2.9	FES may increase people's quality of life, for example, through increasing feelings of self-esteem, capability, wellbeing and participation in life.
2.10	FES may help to strengthen people's muscles.
2.11	FES may reduce stiffness in people's muscles and joints while using FES.
2.12	FES may help people become fitter.
2.13	Once a person is wearing FES, it may make it easier for them to do some things more independently.

3 Considerations and precautions when using FES

Within the Stakeholder Consultation and the Delphi Study people raised the importance of discussing the potential challenges when using FES, partly to manage expectations, and also to ensure that people can make fully informed decisions. Some people find the sensation of FES too unpleasant to tolerate, while others find it difficult to use, or find that their skin reacts to the electrodes. People have to balance the positive and negative aspects and make individual decisions, supported through honest conversation with the FES provider. This was seen to further reinforce the importance of people being offered the opportunity for assessment. The factors that influence appropriateness, safety and acceptability of FES are less likely to relate to the person's specific upper motor neurone condition and more likely to relate to how it manifests (e.g. tone), any other health conditions the person has (e.g. heart condition) and factors such as their understanding, motivation and social support.

Exploration of people's views is very important for this section of recommendations.

Quantitative research has strengths in determining numbers and percentages of people who may experience specific negative effects of using a device such as FES. It would be valuable to develop common monitoring strategies relating to adverse effects, enabling compilation. When looking more holistically at the considerations

involved in decision-making, however, user and provider views are crucial. For example, a quantitative approach may state that there is a lack of evidence for the potential negative effects of using FES during pregnancy. When reading the views of people who use and provide FES, it becomes clearer that such a decision is based on a person's specific circumstances and the potential that risk of falling due to stopping use of FES may be greater than risk of any other potential harm from using it. The evidence from rigorously collected Stakeholder and Delphi Panellist views has provided information about scenarios that should be considered carefully in discussion with the person who considering use of FES or already using it.

3.1	When talking to people about whether FES may be of benefit to them, it is important to put this in the context of the commitment needed in making sure it is set up as well as possible for them, learning to use it, and strengthening the stimulated muscles, which may take time and require repeat appointments.
3.2	When talking to people about whether FES may be of benefit to them, it is important to clarify whether they are using it as a short-term rehabilitation tool, or to support their walking daily for the foreseeable future.
3.3	Where people will find it difficult to engage with the process of learning and problem-solving in relation to FES use, assessment for FES to support walking must include discussion of how this will be supported.
3.4	If FES is being used to support walking and a person is not able to stand up from sitting independently, the assessment must include discussion of how this will be managed.
3.5	Severe joint stiffness or fixed contractures at the ankle can be a reason not to use FES with a person.
3.6	Poor skin condition or skin lesions where electrodes are placed are reasons not to use FES with a person.
3.7	If a person has known history of cancer in the region where FES will be applied discussion of the relative risks and benefits would be required.
3.8	If a person has a known health condition relating to their heart or blood pressure discussion of the relative risks and benefits of using FES would be required, as for any new exercise intervention.
3.9	A person with a pacemaker should consult a cardiologist to get clearance to use FES.
3.10	Due to the lack of evidence which supports the safe use of FES during pregnancy, discussion of the relative risks and benefits would be required.
3.11	It is important for people who provide FES to be aware of Autonomic Dysreflexia (increased blood pressure and very low heart rate) and its management, to make sure that this is considered where appropriate in assessment and monitoring of people using FES.
3.12	When talking to people about whether FES may be of benefit to them, it is important to discuss the possible negative impacts/ adverse events.
3.13	Some people find that when they start to use FES it can be uncomfortable and difficult to use.

3.14	FES can affect muscle spasm and/or spasticity in different ways and it is important to discuss this with people who may be affected.
3.15	FES can affect pain in the muscles or joints during walking in different ways and it is important to discuss this with people who may be affected.
3.16	Some people experience skin irritation under FES electrode pads and may need to use strategies to minimise this.
3.17	If a person develops recurrent adverse events (negative impacts), FES use should be stopped.
3.18	If a person develops any of the listed reasons for not using FES, its use should be stopped while the reason persists.

4 Access to FES services

In both the Stakeholder Consultation and the Delphi Study varied stakeholders described barriers to accessing FES services. These related to service boundaries, funding sources e.g. focusing on different health conditions, local availability of services and awareness of FES among potential referrers. Although the NICE (2009) clinical guidelines referring to all upper motor neuron conditions when recommending FES, funding and decisions about access still frequently vary by condition. These issues are likely to have influenced the strong response in the Stakeholder Consultation emphasising the importance of including information on pathways to access FES services within the CPG. People believed that actions to address awareness and access should be part of FES service design and activities. It was also clear from the Delphi Panel responses that access to FES services follows different routes across the UK and internationally. This is strongly influenced by funding mechanisms and health systems.

It is useful to note that issues around access to FES service provision benefit from a more qualitative approach to exploring Stakeholder and Delphi Panellist views. Some quantitative information would be valuable to providing a description of the scenario more widely – across the UK and internationally. This would be a useful area for future research.

4.1	FES service provision should ensure that people who have the ability to refer to a FES service are aware of the service and have the referral criteria.
4.2	FES service provision should promote their service more publicly using different media so that people who may benefit from FES are aware of it.
4.3	FES services should provide information on how people can seek funding of FES if this is not available through the service.

5 FES service provision

The Stakeholder Consultation and Delphi Study both provided evidence that stakeholders would value a specific and detailed CPG which included information on optimal service design. It was hoped that this would support advocacy for new FES

services and ongoing service improvement of existing FES services. Within this, stakeholders emphasised the importance of having flexibility about how FES is used, and of ensuring that FES services either incorporate or collaborate with other types of service so that a person's holistic needs are considered. Strategic thinking is needed to ensure that financial implications of ongoing equipment provision are considered within any funding arrangements. It is possible that people may need support to locate appropriate funding. People also raised the value of peer support as a potential way to enable people to problem-solve and adapt to FES use.

Delphi Panellists raised the issue that while physiotherapists are commonly involved in FES service provision in the UK, this is not always the case and internationally there is more variation. This has implications for how holistic a service can be, depending on the nature of the service. It was agreed, however, that people using FES should receive holistic support. In many contexts this will require communication and/or collaboration with other services and possibly supportive signposting. It would be useful to do a descriptive service mapping exercise in the future to provide further information on what is available in different areas within and beyond the UK.

5.1	FES service provision (Funding and referral criteria) should not vary between people with different health conditions unless the health condition is a reason not to use FES.
5.2	FES service provision should consider the whole person and all their needs, rather than only the function of walking.
5.3	FES services should include conversations with the person about what they hope to gain from using FES and how to support them in overcoming possible barriers to learning and continuing to use FES over time.
5.4	FES service provision should consider a person's physical impairments and functional deficits and include appropriate strategies to support them.
5.5	FES service provision should consider how FES can support a person in their activities of daily living and include strategies to support their capabilities in these.
5.6	FES service provision should consider whether there are other ways in which physiotherapy and other services may benefit the person and whether this can be delivered within the service or a referral can be made to another service, for example, gait training.
5.7	FES service provision should consider including mechanisms to enable peer support in using FES.
5.8	FES service provision should include appropriate risk assessment and strategies/ policies to reduce risks that have been identified, for example, in relation to a person's understanding of how/what/when to use FES.
5.9	FES service organisations should include financial planning to ensure an appropriate supply of FES devices and consumables as well as maintenance contracts to support existing and new FES users.
5.10	FES service organisations should consider sustainability through recycling of FES devices where fit for purpose.

5.11	A FES service organisation should include administrative support to enable responsiveness to patient needs.
5.12	Guidance should be provided to people who use FES for what to do if they experience difficulties when the service is not open (for example, at the weekend).

6 Initial assessment and treatment

In the initial Stakeholder Consultation views were provided about the importance of having sufficient time for assessment, fitting and education on FES use, as well as sufficient early follow-up to make adjustments. People emphasised the importance of ensuring that people feel confident in using FES. Both Stakeholders and Delphi Panellists emphasised that a person-centred approach is needed in the assessment process and initial stages of use. People absorb information at different rates and need different amounts of time to practice use and adjust to FES. They explained that it can take time to adapt to the sensation, to achieve the amount of movement possible, and to become more confident in using it. Without staged support, FES can be rejected early on or discarded after the early stages of use, despite its potential to help. Again, this form of insight is best achieved through hearing people's views, giving a picture of the variability of need among FES-users when developing confidence in using FES. Further research into optimal strategies for supporting people in the early stages of using FES would be valuable.

6.1	The initial assessment should consider the possible alternative devices available (e.g., also ankle foot orthoses) and positive and negative aspects of each.
6.2	The initial assessment should evaluate whether a person is able to understand how to use FES or lives with someone who can help.
6.3	During the initial assessment the therapist should find out whether it is possible to use electrical stimulation to lift the foot into a right-angle position (dorsiflexion) with the outside 'edge' of the foot slightly higher than the inside (eversion), or to help bend the knee.
6.4	During the initial assessment the therapist should find out whether the person requires support to put the device on and whether this is available.
6.5	During the initial assessment and subsequent appointments the therapist should find out whether the person can tolerate / accept the sensation of electrical stimulation.
6.6	During the initial assessment and subsequent sessions the therapist should explore what the person hopes to gain from using FES and how to support them in overcoming possible barriers to learning and continuing to use FES over time.
6.7	During the initial session the FES provider should educate the FES user on strategies to ensure safe use.
6.8	During the initial session the FES provider should inform the FES user that FES devices are individualised to the person and should not be shared with other people.
6.9	The FES providers should conduct a holistic assessment of the person to explore their broader health and wellbeing needs.

6.10	In the initial session or subsequent session the FES provider should work with the FES user to optimise the settings of the device for that person and practise its use.
6.11	In the same session or subsequent session the FES provider/ service should provide training on how to use FES in daily life.
6.12	In the initial session, or a subsequent session, FES services should ensure that people know how to access ongoing support and when to do so.
6.13	FES services should ensure that any person who is involved with the FES user (e.g. carer, guardian) is included where appropriate, in line with the preferences of the FES user.
6.14	FES services should ensure that FES users have received sufficient assessment, training and education to ensure that they are competent in using the FES device before being given the device to use independently.

7 Monitoring and ongoing support

Regular review and monitoring were raised as crucial aspects of FES provision within the Stakeholder Consultation and Delphi Study. Specific durations of sessions and intervals for follow-up differed somewhat between participants, however, FES users emphasised the value of a person-centred approach within these sessions and having an ongoing point of contact. Without ongoing support there is a risk of people discarding FES as their needs change, despite its flexibility. New risks may develop over time and without regular review these cannot be managed appropriately. Delphi Study panellists emphasised that some follow-up can be online, enabling people who live further away from a service to engage more easily with it. Most monitoring strategies will benefit from the person attending the service in person, however. The importance of people's stories from experience as a user and as a provider are crucial to understanding people's needs. Quantitative monitoring information can be valuable to understanding impact and making a case for funding of services. The value of such information would be strengthened if there were a common set of monitoring strategies that address changes in function and participation over time. Further research and development are needed to enable this.

7.1	FES services should carry out in-person/telephone/online follow-up session with FES users within the first six weeks of use and on a planned basis for as long as the device is used.
7.2	During the in-person/telephone/online follow-up sessions the therapist should explore whether the person is safe when using FES and is not experiencing negative effect.
7.3	During in-person/telephone/online follow-up sessions the therapist should explore whether any further adjustments are needed to the FES device to enable the person to manage better and/or more safely and/or comfortably.

7.4	During the in-person/telephone/online follow-up sessions the therapist should explore whether the person is experiencing falls or fear of falling.
7.5	During the in-person/telephone/online follow-up sessions the therapist should explore any changes in walking and balance related measurement.
7.6	During in-person/telephone/online follow-up sessions the therapist should explore any changes in lower extremity motor function, for example, due to a new health condition.
7.7	During the in-person/telephone/online follow-up sessions the therapist should explore any changes in walking distances in the community.
7.8	During in-person/telephone/online follow-up sessions the therapist should explore progress towards the person's personal goals.
7.9	During in-person/telephone/online follow-up sessions the therapist should explore impacts on the person in relation to their activities of daily living, life roles and quality of life.
7.10	FES services should provide ongoing telephone/online and technical support for FES users while they are still using the device.

8 Minimum training for FES providers

It was clear from the Stakeholder Consultation that all participants wanted to have the assurance that people providing FES had appropriate knowledge and expertise. There was debate within this study and the Delphi Study in relation to what should constitute a minimum amount of initial training and continuing professional development; however, it was clear that this was seen as an expectation for which a FES provider should take professional responsibility. There was reluctance to make expectations too restrictive, which may only serve to reduce access for people. It is, however, important for safety that FES providers have specific knowledge and expertise, which will be supported by availability of a specific CPG. Increasing availability of training and clarity of expectation in relation to capabilities for provision of FES are areas for further development. Provision of different remote strategies to support novice FES providers should be explored.

8.1	FES providers should receive at least one day of initial training in using the specific FES device that they wish to work with.
8.2	People who have not completed a device-specific training course should not be able to provide FES devices for the purpose of supporting a person's walking.
8.3	FES providers should be clinicians with appropriate healthcare training, knowledge and experience in relation to the health condition underlying the need for FES, and training in FES provision, or working under the supervision of such clinicians.
8.4	FES providers should take professional responsibility for undertaking appropriate continuing professional development relating to FES provision to maintain their competencies.

8.5	FES providers should maintain their practice in relation to FES provision and be able to demonstrate that they are using their skills regularly.

6. Clinical Practice Guideline Implementation and Review

Following development of a first Clinical Practice Guideline with this particular focus, it is important to develop plans for:

1. Promoting awareness, implementation and impact
2. Developing priorities for further research to inform ongoing development of the CPG
3. Establishing a timeline for review and revision of the CPG.

6.2 Promoting awareness, implementation and impact

This CPG is available open access online to enable optimal access by all stakeholders. An impact plan is being enacted to ensure dissemination to different stakeholders. This began during its development, as the process of involving people in the Stakeholder Consultation and Delphi Expert Panel involved wide promotion using social media, newsletters, websites, email, conference presentations and webinars. This involved ACPIN and interested Physiotherapy organisations internationally, IFESS, existing FES services, and organisations that work with and for people who have potential to benefit from FES.

A further plan for disseminating the completed CPG document has been developed that uses similar strategies and can refer people to this online document. It is important to note that the CPG document will be updated beyond its initial dissemination, to include links to the publications that provide greater detail relating to the Evidence Review and the Delphi Consensus Study.

Our impact aim is for all physiotherapists and other health professionals in the UK who are using, or considering using, FES in the treatment of their patients to have access to and have read the guidelines. Our target is to achieve 80% saturation within 12 months of publication.

To achieve this impact we will:

- Publish the guidelines on the ACPIN website, distributed through ACPIN networks;
- Facilitate discussion by launching the guidelines;
- Promote guidelines among key stakeholders through professional and service user networks and social media, research centre briefs and university media releases;
- Publish a project outcomes report through the CSP website;
- Submit outputs for publication in a peer-reviewed (ideally open-access) journal and at conferences including PhysiotherapyUK, ACPIN Conference, Neurorehabilitation and Neural Repair Conference; Rehab Week;

- Use the guidelines in training courses; and
- Advocate for inclusion in professional programme curricula.

We will evaluate our impact through surveying awareness and use one year after publication. We plan to seek further funding to qualitatively and quantitatively explore direct impacts on people who use FES.

6.3 Developing priorities for further research and development to inform practice and ongoing development of the CPG

It is important that evidence gaps identified through this CPG development journey are explored further. Some gaps have been raised in response to the development of CPG statements:

- Systematic reviews of the literature focusing on impacts of FES use for people with Parkinson's, Traumatic Brain Injury, or adults with Cerebral Palsy.
- Further research focusing on use of FES in early rehabilitation to support mobility.
- Economic analysis of the impacts of FES use, e.g. in relation to falls reduction.
- Development of standard monitoring strategies relating to adverse effects, enabling compilation.
- Descriptive mapping of existing FES services across the UK and internationally.
- Further research into optimal strategies for supporting people in the early stages of using FES.
- Development of standard monitoring strategies that address changes in function and participation for FES users over time.
- Increased clarity of expectation in relation to capabilities for provision of FES.
- Exploration of remote strategies to support novice FES providers.
- An audit tool should be developed to enable benchmarking of services against this CPG and support ongoing service improvement activities.

This list is not comprehensive, however, and it would be valuable to carry out a research priority setting exercise. This could draw on the expertise of James Lind Alliance Priority Setting Partnerships (2022).

6.4 Establishing a timeline for review and revision of the CPG.

It is necessary to ensure that CPGs are reviewed and revised where appropriate and the need for this will be explored by ACPIN after five years. An updated working group will evaluate the amount of new research and conduct a Stakeholder Consultation to inform this decision, which will then be communicated.

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8. Appendix 1: Credentials and potential conflicts of interest of contributors to development of the Clinical Practice Guideline

Names (alphabetical order)	Role(s) in the CPG Development Process	Affiliation, expertise, relevant professional memberships	Potential conflicts of interest
Adine Adonis	CPG Working Group member; co-researcher/author of initial stakeholder consultation; Delphi Study Steering Group	Chair ACPIN Imperial College Healthcare NHS Trust University College London Member of the Chartered Society of Physiotherapy	None
Gad Alon	Delphi Study Steering Group member	Associate Professor, Emeritus University of Maryland, School of Medicine Department of Physical Therapy & Rehabilitation Science Member of the American Physical Therapy Association (APTA) and International Functional Electrical Stimulation Society (IFESS)	None
Georgia Andreopoulou	Co-author of the Overview of Systematic Reviews	Research Fellow, Centre of Health, Activity and Rehabilitation Research, HCP	None
Ines Bersch-Porada	Delphi Study Steering Group member	Head of International FES Centre® for treatment and education. Member of: IFESS - International Functional	None

		Rehabilitation Society; DMGP - German speaking Society of Paraplegia; ISCOS - International Spinal Cord Injury Society.	
Cathy Bulley	Leadership role in the CPG Working Group; lead researcher/ author of initial stakeholder consultation; Co-author of the Overview of Systematic Reviews; Lead Researcher on Delphi study	Professor in Health Sciences; Co-Director of the Centre for Health, Activity and Rehabilitation Research at Queen Margaret University; Member of the Chartered Society of Physiotherapy; Health and Care Professions Council Member; published research exploring people's experiences of FES	No affiliation with any specific FES device company. Founding co-director of a social enterprise called 'Health Design Collective' who are developing a footwear product for people with foot drop. This aims to support people who cannot benefit from FES.
Jane Burridge	CPG Working Group Co-author of the Overview of Systematic Reviews; co-researcher/ author of initial stakeholder consultation; Delphi Study Steering Group member	Visiting Professor of restorative Neuroscience at the University of Southampton	Research collaborator with Odstock Medical e.g. https://doi.org/10.1111/j.1525-1594.1997.tb04662.x
Giulia Busselli	Lead author on the Overview of Systematic Reviews	At the start of the overview: Department of Neurosciences, Biomedicine and Movement Sciences, University of Verona, Italy; UOC Neurorehabilitation, AOUI Verona, Italy. Currently: Physical and Rehabilitation Medicine specialist in Unità Operativa Complessa di Medicina Fisica e Riabilitazione, Azienda ULSS9	None

		Scaligera, Verona, Italy.	
Eleanor Curnow	Delphi Study Steering Group member	Research Fellow, Queen Margaret University, Member of the Royal College of Occupational Therapy; Health and Care Professions Council UK	None
Sean Ewings	Co-author of the Overview of Systematic Reviews;	Associate Professor of Medical Statistics Southampton Clinical Trials Unit	None
Vicky Fenerty	Co-author of the Overview of Systematic Reviews;	Research Engagement Librarian at the University of Southampton	None
Sarah Joiner	CPG Working Group member; Delphi Study Steering Group member	Person with lived experience Vice Chair Trustees, Multiple Sclerosis Trust	None
Claire Meagher	Co-researcher/ author of initial stakeholder consultation;	Currently: Senior Research Officer at Office for National Statistics - Health Analysis and Life Events; at the time of involvement: Researcher at the University of Southampton with appropriate research experience relating to FES and research methods	None
Carla Peace	Co-researcher/ author of initial stakeholder consultation;	Specialist physiotherapist in FES at West Midlands Rehab Centre, MCSP, HCPC Member, published research in the use of FES in treatment of constipation.	None
Christine Singleton	Co-researcher/ author of initial stakeholder consultation; Delphi Study	FES Service Lead, Clinical Specialist & Project Manager Functional Electrical Stimulation (FES) Clinic	None

	Steering Group member	Birmingham Community Healthcare NHS Foundation Trust. Member of the Chartered Society of Physiotherapy; Health and Care Professions Council Member; Member of the Organisation of Chartered Physiotherapists in Private Practice	
Tamsyn Street	Leadership role in CPG Working Group; Co-author of the Overview of Systematic Reviews; co-researcher/ author of initial stakeholder consultation; Delphi Study Steering Group member	Salisbury NHS Foundation Trust. Visiting Fellow Bournemouth University, Visiting Fellow Indiana University-Purdue University Indianapolis International Functional Electrical Stimulation Society (IFESS) Executive Board Member	Salisbury NHS Foundation Trust has shares in Odstock Medical a medical device company which designs and manufactures electrical stimulation devices and provides clinical care to patients
Paul Taylor	CPG Working Group member; Delphi Study Steering Group member	Consultant Clinical Scientist at The Department of Clinical Science and Engineering, Salisbury District Hospital; Clinical Director of Odstock Medical Limited; Visiting Professor at Bournemouth University, Faculty of Health and Social Science.	Clinical Director of Odstock Medical Limited, a company that manufactures and supplies FES Equipment and clinical servicers. Odstock Medical Limited is majority owned by Salisbury NHS Foundation Trust.
Marietta van der Linden	CPG Working Group member; Co-author of the Overview of Systematic Reviews; Delphi Study Steering Group member;	Professor in Health Sciences; Co-Director of the Centre for Health, Activity and Rehabilitation Research at Queen Margaret University; Research. Expertise in physical activity and assistive technology to treat foot drop in people with neurological	None

		conditions. Member of Rehabilitation in MS (RiMS)	

MCSP: Member of the Chartered Society of Physiotherapy (UK)

HCPC: Health and Care Professions Council (UK)

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