When should an intervention be provided?

The questions of whether, when, and how much to provide of a health care intervention are central to decision making across all levels of health care, from government through to individual clinicians. A recent Editorial in *Australian Journal of Physiotherapy* declared that the benefit-harm trade-off method (Barrett et al 2005) was a ‘clearly superior’ approach to determine whether effects of an intervention were clinically important (Ferreira and Herbert 2008). This is a contentious position deserving further exploration.

The benefit-harm trade-off method involves presenting patients with a series of hypothetical scenarios where the benefits of an intervention are varied while costs, harms, and inconveniences of the intervention are held constant. From the perspective of a health economist, the point at which a clinical effect is sufficient to warrant implementation could be argued as being the point at which the benefits obtained from its provision outweigh the costs. The cost-benefit analysis approach directly addresses this question by (to simplify) placing a monetary value on the costs incurred consequent to provision of the intervention, and weighing this against a monetary valuation of the health benefits gained (Drummond et al 1993). To this point, the underlying concept of cost-benefit analysis is consistent with that of the benefit-harm trade-off method. However, cost-benefit analysis is typically undertaken from a ‘societal’ perspective in line with welfare economic theory rather than from the ‘patient’ perspective, meaning that a broader set of costs and benefits are considered. Patients are rarely the sole stakeholders and decision makers in decisions about health care provision and utilisation. The decision to make available particular health care services is commonly made by health care administrators and professionals rather than by individual patients. The expectations of individual patients also cannot be expected to represent the views of the other stakeholder groups that fund healthcare programs such as governments, insurance companies, and the tax-paying public.

The benefit-harm trade-off method requires patients to understand fully the costs and consequences of the scenarios put before them to be able to make an informed decision. There is a balance between depth of explanation and potential for participants to remember and integrate all of this information into their decision-making process. Hence this approach is likely to have limitations when applied to patient populations with limited cognitive processing capacity, or for evaluation of complex health care interventions, or interventions with a range of potential side effects or benefits.

So, what value then are distribution- and anchor-based approaches to calculating a minimally important difference? Anchor-based approaches attach implicit ‘meaning’ to units of change on a measurement scale by explaining what impact this amount of change has on the ‘anchoring’ variable. This can be important from multiple stakeholder perspectives. Hypothetically, an increase of 1 point on a 10-point visual analogue scale of cancer-related fatigue may be associated with a 4 hour reduction in the number of hours per week that person is able to work at their occupation. For an employer, this means half a day in lost production. For a government, less economic activity results in less taxation revenue to fund healthcare and other services. Another example is that a 10-point change in the Functional Independence Measure corresponds to a halving of the time required to care for a person following stroke (Granger et al 1993). Distribution-based approaches are useful adjuncts to anchor-based approaches. Rather than providing a new clinical meaning, they are useful for confirming the rationality of application of the clinically important differences selected through anchor-based approaches. If the Standard Error of Measurement of our cancer-related fatigue scale = 2, then we would have 68% confidence that an individual patient’s true score fell within ± 2 points and 95% confidence that the individual’s true score fell within ± 4 points of the observed score. Thus, if we observed that an individual reduces their level of cancer-related fatigue as a result of our intervention by a value of 1 point, we must consider whether we have observed a real, clinically important change, or simply measurement error.

There are many potential applications of a clinically important difference developed through anchor-and distribution-based approaches to assist with decision making. These are not limited by the patient population, complexity of intervention, or breadth of benefits and side effects. Despite the concerns we have raised regarding the benefit-harm trade-off method, we view it as also being a potentially useful tool for aiding clinical decision making. Rather than create a hierarchy of approaches, we advocate the use of a range of tools to aid decision making with due acknowledgement of their purpose, strengths and limitations.

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References


Clinical importance of an intervention must reside with the patient

We thank Haines and colleagues for their interest in our Editorial. While we agree with much of what they say, we feel that their letter misses the point of our Editorial. So we are grateful for the opportunity to make our point more clearly.

We argued that an intervention is clinically important if it has effects that are large enough to make the costs, inconvenience, and harms associated with intervention worthwhile (Ferreira and Herbert 2008). Decisions about clinical importance need to be made by patients with the assistance of health professionals because they need to take into account how patients value both the costs and benefits of intervention. We reiterate that distribution- and anchor-based methods do not help physiotherapists to make clinical decisions because they do not provide a voice to the person who ultimately must agree to the intervention. Ultimately clinical importance must be assessed from the perspective of the person who is seeking health care.

Haines et al argue that decisions about whether, when, and how much to provide of a health care intervention have societal impacts, so they should be based on societal perspectives. The benefit-harm trade-off method cannot provide a societal perspective so it cannot be used in isolation to inform decisions about whether, when, and how much to provide of a health care intervention. Unlike the benefit-harm trade-off method, anchor-based and distribution-based methods can provide data that can be used to model societal impacts.

We acknowledge that it is necessary to consider societal impacts in many contexts and, when that is the case, distribution- and anchor-based methods can provide data complementary to information about clinical importance. These data can inform decisions by service providers about the allocation of health care resources. In other contexts it might not be necessary to consider societal perspectives. For example, private care providers arguably need to have little interest in the societal impacts of an intervention.

An important limitation of the anchor-based approach was not acknowledged by Haines and colleagues. Anchor-based approaches cannot inform decisions about whether the effect of an intervention is clinically important, because effects of intervention can only be understood in terms of between-group differences. In contrast, anchor-based approaches attach a meaning to the change in outcome patients experience over time. Using anchor-based approaches to make decisions about the clinical importance of effects of intervention involves using estimates derived from within-group changes to interpret between-group differences. This could be very misleading.

Manuela L Ferreira and Robert D Herbert

References

Did authors draw the right conclusion?

Wand and colleagues (2009) show insight in recognising the need to study directional patterns as reported by patients. Exploring aggravating factors is a universal practice, yet formal study in this area is lacking. The importance of bias in the process is also wisely brought to our attention in this work. The authors concluded ‘there is no evidence for the existence of a consistent direction of spinal movement during the self-reported aggravating factors.’ We offer three areas for further discussion:

1. The authors made a good case for the heterogeneous nature of low back pain, so we were surprised that they appeared to expect a ‘consistent’ pattern. Different subgroups perhaps should have been expected. They appear to underestimate the importance of their primary finding (32% of patients reported a directional pattern). In chronic patients, the ability to identify a subgroup as large as 32% could be an extremely important finding. A better conclusion might have been ‘Using the Patient-Specific Functional Scale identified a subgroup of chronic low back pain patients that is at least as large as 32%.’ The next step is to validate this subgroup and study them in randomised trials.

2. This work does not correctly represent how subjectively-reported directional patterns are interpreted clinically. These ‘clues’ are provisional and the classification systems mentioned rely on their physical examination findings to make the final classification judgement. A better conclusion would be that the PSFS is inadequate as a classification tool (perhaps because it has been designed and validated as an outcome measure?)

3. Unfortunately 127 participants were excluded and, therefore, results were based on a potentially biased sample. This partly relates to the retrospective nature of the data analysis, with a meaning being ascribed to data that were not collected for this purpose.

These 127 participants may have been included if simple investigative follow-up questions were included. While we respect the authors’ attempt to control for confi rmatory or illusory bias, the questioning may have been so restricted that important ‘data’ were missed. Example: the following two patients would have been excluded as not having a directional pattern: worse vacuuming, walking, and sleeping (flexion, extension, and unclassifiable as per Table 1.)

Possible follow-up questions and answers are:

- Where does it hurt when you vacuum? Answer: Just in my back, 2/10.
- Where does it hurt when you walk? Answer: My whole leg, 7/10.
- Which sleep position worsens your leg pain? Answer: On my stomach.

With more information, classification = worse with extension.

Alternatively we could ask:

- How long will you stay sore after you vacuum? Answer: All day.
- How long will you stay sore after you walk? Answer: Actually it only hurts for the first 5 minutes. The more I walk the better I feel.
- Does it matter which position you sleep in? Answer: I’m better on my stomach.

More information = relief extended.

Bias is a very important issue and we hope the next step would be to explore the effectiveness and bias of various interview strategies. We can only speak to the system with which we are most qualified, Mechanical Diagnosis and Therapy (otherwise known as the McKenzie Method). The following strategies are encouraged but would benefit from formal study:

- Use open ended questions including What makes you feel better?
- Always ask the effect of a variety of activities, not just your favourite eg, bending, sitting, standing, walking, ADLs, and lying positions
- Avoid leading questions eg, Are you worse when you sit?
- Use clarifying questions if patients say sometimes or sort of.

The topic of classification bias in interview methods does need to be explored further. Additionally, follow-up questions and bias in various physical examination methods should also be examined. Wand and colleagues have begun an important path of investigation.

Audrey Long1 and Stephen May2

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Reference

The conclusion was drawn from the data

We thank Long and May for their careful consideration of our research paper (Wand et al 2009) and we particularly welcome their concluding remarks. It is very encouraging to see research being integrated into practice so rapidly and appropriately. Long and May raise three points about our conclusions which we would like to comment on briefly.

1. We did indeed find that 32% (95% CI 24% to 40%) of the sample demonstrated a directional preference; however, we are less sure that this represents an ‘extremely important finding’. Our enthusiasm for this finding is tempered by the fact that it is not significantly different from what would be expected to emerge by chance. This finding may represent ‘noise’ rather than a clinically meaningful phenomenon. Importantly this figure includes all those who demonstrated a preference regardless of direction. We do not think this small proportion is verification that chronic non-specific low back pain can be sub-grouped in this way. We agree that this result is open to other interpretations, but it might explain why randomised trials utilising treatment models that categorise patients by directional preference have shown such disappointing results (Machedo et al 2006, Klaber Moffett et al 2006, Paatelma et al 2008).

2. We do not consider the results of our study to offer definitive information on the validity of classification by directional preference and are in complete agreement with Long and May on this point. This requires a concerted research effort utilising a variety of methodologies exploring a number of the predictions associated with these approaches. We state in our discussion that ‘the inclusion of additional clinical testing may change the results presented’ and we certainly think the points made by Long and May would be welcome additions to the assessment process. However, to conclude that the Patient-Specific Functional Scale is an inadequate classification tool because it fails to demonstrate the hypothesised sub-groups, presupposes that these sub-groups exist – and this has yet to be demonstrated convincingly.

3. Bias must always be considered when participants are excluded, however we feel that the reasons for exclusion are unlikely to represent a threat to the findings presented. To confirm this we have analysed the results from the 92 excluded participants (not 127). Six participants had one or less classifiable tasks and so could not be used. In the remaining participants with two classifiable tasks, the results are identical to those presented in our paper. There were a number of participants who demonstrated a directional preference, but this figure was the same as would be expected by chance.

We again thank Long and May for their insightful and important comments on our paper.

Benedict M Wand, Rebecca Hunter, Neil E O’Connell and Louise Marston

References

Is progressive resistance exercise ineffective in increasing muscle strength in young people with cerebral palsy?

What is surprising and challenging about the systematic review of Scianni et al (2009) is the finding that strengthening interventions, including progressive resistance exercise, are ineffective in increasing muscle strength in young people with cerebral palsy. This finding is surprising as it is contrary to the conclusions of previous systematic reviews that progressive resistance exercise is effective in increasing muscle strength in people with cerebral palsy (Dodd et al, 2002), and across diverse populations in physiotherapy practice (Taylor et al, 2005). The finding is challenging because if an intervention does not achieve its primary purpose, in this case to increase muscle strength, then further discussion about whether the intervention can affect more meaningful things, like the ability to carry out daily tasks, is meaningless.

One explanation for this apparently contrary finding is that the review of Scianni et al (2009) only included controlled trials, whereas the review of Dodd et al (2002) included studies with single group pre-post designs, designs that are more subject to bias. Therefore, it is possible that the review of Dodd et al (2002) may have overestimated the true effect of progressive resistance exercise. A second consideration, acknowledged by the authors of the review, is whether the interventions provided a sufficient stimulus to provide a strengthening effect. One of the three included trials that evaluated resistance exercise, that of Liao et al (2007), reported that participants completed between 20 and 100 repetitions of their sit to stand exercise (at a load of 50% of one repetition maximum) during each session. Such a dosage is not consistent with guidelines for increasing muscle strength: that the load should be such that no more than 8 to 12 repetitions can be completed before muscular fatigue (American College of Sports Medicine, 2002). The training dosage described by Liao et al (2007) is more consistent with a dosage designed to practise a skill or increase muscle endurance, but not to increase muscle strength. Also, two other trials included in the analysis of muscle strength by Scianni et al (2009) investigated the application of electrical stimulation. The authors of those trials questioned whether the intensity of the stimulation was sufficient to achieve a strengthening effect. Therefore, there are questions about whether three of the five trials included in the analysis of muscle strength provided an intervention with sufficient intensity to increase muscle strength. Also, because the five trials included in the analysis on muscle strength included three distinct interventions (progressive resistance exercise, endurance training, and electrical stimulation) is it reasonable to combine them in a meta-analysis?

A third consideration concerns the method of calculating effect sizes (standardised mean differences) and whether this led to some anomalous findings. Scianni et al (2009) calculated effect sizes on post-intervention means according to the recommend method (Higgins and Green, 2008). For McCubbin and Shasby (1985), the effect size estimated on the post-intervention means was 0.69 (95% CI –0.21 to 1.63), indicating a non-significant effect. This is in contrast to the author’s original report of a significant effect in favour of progressive resistance exercise, and data that the intervention group increased strength by 58.9% and the control group reduced strength by 5.3%. So what is going on? Calculation of effect sizes based on changes from baseline on the same data results in an effect size of 1.63 (95% CI 0.62 to 2.64). Similarly, re-calculation of the effect size based on changes from baseline for Dodd et al (2003) results in an effect size of 0.74 (95% CI –0.15 to 1.63), in contrast to an effect size of 0.07 (95% CI –0.79 to 0.93) if calculated on post intervention means. The main point is that the same data in controlled trials with very small sample sizes (the two trials described here only included a total of 21 participants in the strengthening groups) can lead to very different estimates of effect according to the method chosen.

A hallmark of good research is to raise questions and challenge accepted practice. Scianni et al (2009) are congratulated for completing a high quality systematic review that raises questions and challenges the use of progressive resistance exercise, and other strengthening interventions, as a treatment option for young people with cerebral palsy. However, given the questions about whether the interventions were applied with sufficient intensity, whether it is reasonable to combine interventions with clinical heterogeneity in a single meta-analysis on the effects on muscle strength, and given questions about how the method of calculation of effect sizes on the same data can result in very different interpretations, is it reasonable to conclude, as the authors have done in the title of their review, that muscle strengthening is not effective in children and adolescents with cerebral palsy?

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References

Is there sufficient evidence?

We read with interest this article (Scianni et al 2009) and compliment the authors on their systematic review. However, as researchers in the field we wish to make two points.

The number of randomised clinical trials in the area is very small which may have led Scianni and colleagues to include an unusual mixture of studies which in our view should not be included in a single review. Specifically, progressive resistance training and electrical stimulation. Strength training is at an early stage in clinical trials in cerebral palsy, especially randomised trials. Like all interventions in cerebral palsy, it takes time to define the appropriate intervention protocol, to identify to whom it may be applicable, and to design appropriate trials with reliable assessment measures and adequate power. We disagree with the conclusion that it is ‘not effective in children with cerebral palsy’. Our conclusion, on review of the studies is that there is insufficient evidence and additional work needs to be done.

The conclusion that ‘strengthening interventions are not worthwhile’ is subjective and is not supported by the data.

It also runs contrary to what participants in previous and current PRST trials in Melbourne are telling us – that PRST is enjoyable, very worthwhile, and something which many adolescents and young adults wish to incorporate in their daily lives, for a variety of reasons. For many adolescences this is a social outlet which makes them feel good about themselves. It is important not to give people unrealistic expectations or claims about the effect of an intervention, but the individual should decide whether it is worthwhile or not. We as able bodied people can attend a gym and commence a training program without it undergoing rigorous scrutiny and we can decide the benefit to us; the same should apply to people with disability. It is a shame that Scianni et al should include such a subjective comment, in their abstract, unsupported by data, in an otherwise scholarly review.

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References

Results present a challenge for clinicians and researchers

Like the letter writers, we found the result of our systematic review (Scianni et al 2009) to be interesting. It came from a rigorous application of a priori definitions and followed the blinding procedures outlined by the Cochrane collaboration.

It is possible to get different results from a meta-analysis using the post-intervention scores rather than the change scores. When using the standardised mean difference when combining trials where the outcome measures use different units (eg, Nm of torque versus points on a 0–5 scale), it is necessary to use one or the other – they cannot be combined. While using the change scores takes into account baseline differences between the groups, most randomised trials do not report them, as was the case in our systematic review. This is one of the reasons that the routine inclusion of change scores and the placement of individual data on the eAddenda of Australian Journal of Physiotherapy is valuable (Herbert 2008) – it allows the inclusion of data into future systematic reviews. Proponents of using post-intervention scores argue that any baseline differences between the groups will be ‘washed out’ across the meta-analysis because some will favour the experimental group and some will favour the control group. Either way, it is important that there is similarity between the groups at baseline – one of the independent items of the PEDro scale for methodological quality of randomised trials (de Morton 2009) – because participants with different beginning levels of impairment may respond differently to the same intervention. In future trials, similarity at baseline may need to be achieved with stratification.

Both letters claim that it is not reasonable to combine different strengthening interventions, but neither outlines why not. We argue that in answering the question of whether strength can be increased in children with cerebral palsy, it is appropriate to include any intervention that is repetitive, involves near maximal contractions, and is progressed as participants’ abilities change – as in our review. Furthermore, a subgroup analysis of only progressive resistance exercise produced similar results. Our second question was whether strength training was worthwhile. For the purpose of this review, this was defined as carryover to the activity level, and in this context, the data support the conclusion that intervention was not worthwhile judged by this measure. Whether strengthening interventions are worthwhile in terms of participant satisfaction and/or quality of life remains to be seen, since it is only recently that these types of outcomes have been measured in clinical trials of physiotherapy intervention.

The meta-analysis shows that the evidence, as it exists at the moment, is that strengthening is not effective. One of the possible reasons for this may be that the intensity of the intervention was not enough, according to the guidelines for strengthening (American College of Sports Medicine 2002). This challenges clinicians and researchers to focus on the dose of their intervention, whether prescribing an individual exercise program or designing a randomised trial. If the questions raised by this systematic review result in future trials being designed to meet the challenges posed, then these will be included in the next meta-analysis carried out to answer the question ‘Is strengthening effective in children with cerebral palsy?’

Aline Scianni, Jane Butler, Louise Ada and Luci Texeira-Salmela

References
Balance exercises in arthritis need to be targeted to the individual

The recent paper by Chaipinyo and Karoonsupcharoen (2009) raises some issues that warrant further discussion and research. Some of these are methodological issues, and some relate to the underlying constructs being addressed by the interventions, and how these were assessed.

From a methodological perspective, a randomised trial was used, with assessor blind to group allocation at each assessment occasion. A sample size of 48 (24 in the home-based strength training, and 24 in the home-based balance training) was recruited. However, despite randomisation, the two groups had moderate differences at baseline (only data for those who remained in the study at followup are provided, n = 24 for the balance group and n = 18 for the strength training group); eg, there were five second differences between the two groups for time to walk 15 m, and the Get Up and Go test. This issue does not seem to have been considered in the analyses or discussion, other than highlighting that all six dropouts were from the strength training group. Those dropping out appeared to have better mobility, leaving a final sample in the strength training group with poorer performance measures.

However, some more fundamental questions need to be asked from a clinical perspective. Some of these relate to the underlying understanding of what constitutes effective standing balance. This leads on to the selection of appropriate measures to detect meaningful change in this domain, and also the composition of the balance training program. Balance is generally considered multidimensional, to include both static and dynamic elements (Huxham 2001, Horak 2006), and that assessment should include evaluation of some of the type of tasks involved in ‘balance failure’ (ie, falls), such as stepping and walking, turning, reaching, or leaning. While measures of gait speed and the Get Up and Go test do incorporate a global measure of some of these elements, we consider a brief suite of clinical tests evaluating each of these domains individually to be more useful, accurate, and sensitive to change, than those selected for this study. An alternative, that would take a similar amount of time but evaluate four aspects of balance and integrate into an overall balance score, is the BOOMER (Haines 2007).

Given the multidimensional aspects of balance, a training program should incorporate more than a stepping task, and a squatting task (which is more a functional strength exercise than a balance task). In the falls prevention literature, the Otago exercise program has been shown to reduce falls in a number of studies of older people with falls risk (with samples including 35% with lower limb osteoarthritis). This program incorporates a tailored/individualised balance (and strengthening) program, with exercises selected to address identified aspects of balance dysfunction or muscle weakness. The majority of the strengthening exercises are also functionally oriented. A final issue with the exercise programs used in this study is that if the study wanted to compare relatively discrete strength training and balance training programs, then the squatting exercise should form part of the strength training program, rather than the balance training program (though, of course, in reality a program for people with arthritis would often incorporate both strength and balance training).

Another important aspect of the intervention in interpreting the outcomes is its duration. Four weeks is a relatively short period to observe change with these exercise programs, and more often periods of three to six months have been reported (Fransen 2007, King et al 1998).

Consideration of all of these factors suggests that the findings of this study should be considered exploratory rather than confirmatory. There is a need for a well designed randomised trial utilising a comprehensive suite of balance assessments, and a tailored balance training program of longer duration, to more clearly articulate the broad range of potential benefits of this approach in people with arthritis. Results from such a study would guide clinicians as to the importance of incorporating balance assessment and retraining into routine practice with people with lower limb arthritis.

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References
Website
We appreciate the comments and discussion from Hill and Williams on our study. We agree that an individualised balance exercise program is ideal for people with knee arthritis who have a high risk of falling. However, resource constraints in some settings may necessitate a simple home-based exercise program that can be generally recommended to patients with mild or moderate knee osteoarthritis. The exercise program in this study is meant to be simple enough for such patients to practise by themselves, allowing it to be a general exercise program that can be distributed in the community.

On most characteristics, those participants who later dropped out did not differ from those who completed the trial. However, Hill and Williams correctly infer that those who dropped out performed better on the time to walk 15 metres, and the Get Up and Go test. We have amended the table of individual data for our trial to include the baseline measures of those who dropped out of the strength training group (see Table 3, Chaipinyo and Karoonsupcharoen 2009). We are able to do this via the e-Addenda feature of Australian Journal of Physiotherapy (Herbert 2008). We did attempt to account for these differences by observing change from baseline as opposed to final values. However, we also acknowledge that a more sophisticated method of dealing with these differences would have been to adjust for these differences as a covariate in our analysis.

To enable comparison of the outcome of this study with other knee OA studies, functional ability measures including walking, Get Up and Go, and walking up and down 11 stairs were used in our study (Chaipinyo and Karoonsupcharoen 2009, Fransen and McConnell 2008, Hurley and Scott 1998). The international consensus statement regarding the core set of outcome measures for phase III clinical trials in OA (Bellamy et al 1997) stated that randomised clinical trials should include self-reported measures of pain, physical function or both. The BOOMER overall balance score has been developed for and validated in the aged rehabilitation setting, including patients with neurological conditions, fracture, and arthritis as a subgroup (Haines et al 2007). The purpose of BOOMER is to measure standing balance. It includes step up, Timed Up and Go test, functional reach test, and static standing with eyes closed. There are some similar outcomes between these two measurements. However, walking up and down 11 stairs, as used in our study, is closer to functional movement than counting the number of steps within 15 seconds, as used in BOOMER (Haines et al 2007).

The training program in our study was aimed at improving pain and functional ability related to knee OA, not specifically to improve fall rates. The Otago exercise program is recommended to prevent falls in people aged 80 years or older who have had a fall in the previous twelve months whereas in our study the mean (standard deviation) age of participants was 66 (7) years. Specific balance training is needed for people at high risk of falls but for younger people, such as in our study, a simple home-based general program could be more applicable to larger populations in the community.

Significant improvements in pain, strength, and functional mobility were found after training for 4 weeks in this study. This may indicate the point where changes can be detected. Therefore we believe it was worthwhile to examine interventions with this duration.

Finally, we agree with Hill and Williams that further well designed randomised trials regarding the effects of balance training in people with knee OA are required to explore the potential benefits of this approach not only on standing balance but also on pain and functional mobility.

Kanda Chaipinyo and Orapin Karoonsupcharoen

References

We would like to elaborate on the recent editorial by Hush and Herbert (2009). It provides an articulate overview of recommended strategies to prevent research fraud with particular reference to the Australian Code for the Responsible Conduct of Research (2007).

First, we draw attention to the relatively new Research Standard 2.5 embedded within the ACHS EQuIP 4 Accreditation program. This Standard is relevant to most private and public healthcare facilities in Australia – given that the ACHS program is the most widespread healthcare accreditation program in this country (Braithwaite et al 2006) – and thus is relevant for most hospital physiotherapy departments. The Standard exists to protect all parties involved in research as well as to promote healthcare research. Whilst a hospital’s research ethics committee provides a form of virtual research governance (directing researchers to many documents to assist interpretation of effective research governance), the onus has been largely on the individual researcher to implement research governance as they understand it. Now, the EQuIP Standard requires that the researcher’s facility takes an active role in research governance, ensuring that anyone involved in research provides tangible evidence of their governance processes and outputs.

This brings us to the second point of this communication. How can the healthcare facility facilitate researcher compliance with the Standard (or, equally, compliance with the Australian Code)? We echo the recommendations highlighted in the Editorial intended to keep the researcher on the straight and narrow, and in our respective roles in our healthcare facilities, we have used them to endorse and implement a practical approach to assist local researchers and clinicians to meet the Research Standard. One arm of the approach is the convening of an interactive Research Development Committee. This committee has multidisciplinary membership with various levels of research and quality improvement acumen. It functions to provide practical guidance about managing and undertaking research as well as to provide feedback to clinicians about their research proposals presented at Committee meetings. It is mandatory that all protocols are presented, preferably prior to an ethics submission, however, the Committee allows flexibility with the timing of the presentation as this provides greater latitude for more experienced researchers who may not require supplemental scientific assessment of the protocol prior to ethics review. In such instances, the primary purpose of the interaction is for the researchers to articulate the means by which risk to the organisation and patients, and protocol violations will be minimised. Another arm of the approach is the development of a Practical Research Governance Checklist (see eAddendum). The checklist is a practical translation of the 2007 Code, purposefully orientating the user to what will suffice as evidence in the event of a spontaneous or planned research audit. A third arm is the creation of a Research Registry serving, amongst other things, to inform all within the facility of what research is being conducted.

Scientific fraud may occur wittingly and unwittingly by the initiated and uninitiated. We hope our ‘Research Governance 101’ approach prevents both.

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**eAddendum:** Practical Research Governance Checklist available at ajp.physiotherapy.asn.au

### References


**Website**

Complex decongestive physiotherapy for pretibial myxoedema

Lymphoedema is a chronic, debilitating disorder resulting from congenital abnormality of the lymphatic system (primary lymphoedema) or acquired causes (secondary lymphoedema). Complex decongestive physiotherapy is the 'mainstay' intervention for lymphatic insufficiency comprising manual lymph drainage, in selected cases intermittent pneumatic compression, multilayered compression bandaging with appropriate padding, exercise, and meticulous skin care (Consensus Document of the International Society for Lymphology 2003). Manual lymph drainage encourages fluid mobilisation, protein reuptake from interstitial space, and softening of fibrotic tissue. Pneumatic compression aids manual drainage. Short-stretch bandages have low resting and high working pressure, which means that contracting muscles will be compressed and aid lymph flow. Exercise while using multilayered compression also aids manual lymph drainage. Once active therapy is completed, patients continue maintenance therapy with custom-fitted stockings. As symptoms become more severe, the active phase has to be repeated.

A 40-year-old-woman with history of Graves’ disease for more than 21 years presented with a progressive enlargement of both legs that significantly impaired her mobility. At the time of presentation for Graves’ disease, she had excessive exophthalmos. Two years after the onset of thyroid disease she underwent partial strumectomy and 6 years ago received two sessions of radioactive iodine with a total dose of 763 MBq and intravenous corticosteroid therapy in repeated two sessions of radioactive iodine with a total dose of 763 MBq and intravenous corticosteroid therapy in repeated cycles. Subsequently, she gained around 18 kilograms in weight. In 1992, a biopsy of the right leg showed epidermal hyperplasia with largely increased dermal mucin. On admission, the patient demonstrated significant, non-pitting, swelling in both legs accompanied by verrucous hyperplasia and multiple, firm nodules giving the skin an accentuated, 'peau d’orange' appearance (Figure 1a). Pretibial myxoedema is a known manifestation of Graves’ disease that occurs in association with diffuse thyroid gland enlargement, exophthalmos, and thyroid acropachy (Kriss 1987). Mild forms of pretibial myxoedema may regress spontaneously, but the rare, severe elephantiasic variant is often resistant to different therapeutic approaches including local and systemic corticosteroids, compression, plasmapheresis, and immunosuppressive agents (Felton et al 2003, Srebrnik et al 1992, Schwartz et al 2002). Structural and functional abnormalities of the lower limb lymphatic system have been found in pretibial myxoedema (Bull et al 1993). Therefore pretibial myxoedema is secondary lymphoedema and this warranted the application of decongestive physiotherapy for this patient. Decongestive physiotherapy comprising 45 min of manual lymph drainage plus another 45 min of intermittent pneumatic compression (30 Hgmm pressure) using Lympha Press Plus™ and multilayered compression bandaging was performed once daily for 5 days in an in-patient setting by a specialised physiotherapist (Szolnoky et al 2008). Two 5-day courses were included over 8 weeks. Volumetry was performed with Kuhnke’s disc model (Földi and Kubik 2000) to determine any reduction in swelling. Knee flexion range of motion, mobility and patient’s perception of swelling were also measured (Szolnoky et al 2007).

After 8 weeks, the patient had lost over 3.5 kg; her right leg volume was reduced by 9% and the left by 11%. The most significant change in appearance occurred around the heels (Figure 1a and b). There was less nodularity and a smoother surface to the legs. Knee flexion increased from 90 deg to 105 deg. Walking speed over 10 m increased from 0.47 m/s (SD 0.03) to 0.60 m/s (SD 0.02). This was accompanied by an increase in step length from 31 cm (SD 1) to 36 cm (SD 1), a decrease in step width from 10 cm (SD 1) to 8 cm (SD 1), and an increase in cadence from 72 to 73 steps/min. Her perception was that the swelling had decreased from 8.3 to 4.5 on a 10-point visual analogue scale. She now regularly takes part in a belly dancing course.

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References