

# Why don't we know more about what we are doing?

There have been huge changes in science and technology in the past 30 years. We now understand the genetic basis of many diseases, and with the complete mapping of the genome, our knowledge will expand tremendously. We have CT, MRI, computer-guided surgery, gait analysis, and a host of other advances which have made medical care for our patients more effective. While these changes have profoundly altered the way patients are cared for, it seems that orthopaedic decision making for treatment of children with cerebral palsy (CP), remains more of an art than a science, and there are few objective criteria for intervention which clinicians agree upon. Then why is it that we seem to be lagging behind in the area of orthopaedic treatment of CP?

CP is a very heterogeneous condition: although we can classify patients with CP into diplegic, hemiplegic, and quadriplegic types there is, within these groups, a wide variation in involvement. Not only is it difficult to measure precisely the severity of involvement, it is even more difficult to assess the patient qualitatively in terms of all aspects of their motor deficit, including spasticity, extrapyramidal involvement, weakness, deficits in coordination, and motor planning, etc. There is a multitude of other factors that will influence outcome of our patients such as motivation, the amount and type of therapy, and exposure to activities which may enhance physical development. Our patients rarely have a single intervention which further confuses attempts to assess impact of a chosen intervention on function.

There are equally complex issues in the area of outcome measurement. We have seen the introduction of a variety of standardized outcome measures in the past two decades, however, only one of these, the Gross Motor Function Measure, is referenced to the child with CP. Although many of these measures are able to detect major changes in function, their sensitivity is limited.

There are many significant obstacles in establishing long-term scientifically sound clinical trials to assess interventions for patients with CP. In the current medical environment, remunerative clinical care is valued to a much higher degree than clinical research unless this research is well funded with generous indirect costs, such as drug studies supported by pharmaceutical companies. Not only does this limit research but results in few clinicians being well trained in clinical research in the area of CP.

If one is able to obtain funding for long-term clinical research there are other obstacles. Participant recruitment is

difficult as it takes a significant commitment of a parent and a child to participate in a research study. Also, although most people in the field realize the necessity of satisfying ethical requirements of clinical research, this can be a very time consuming and frustrating process and seems to become more difficult each year, and with each change of the overseeing committee.

In addition to all of the above obstacles, an even more significant problem is that most of this research is to be done by clinicians who are caring for patients. Many clinicians find it difficult to change their relationship with their patient and family from one where they are a clinical care provider to one in which they are a clinical investigator, who must ask their patient to be randomized to one or another treatment program, when there may be pre-existing biases of that clinician.

A final critical issue in assessing outcome of interventions is that we lack understanding of what our patients really want in terms of their ultimate outcome. Do they really care about decreased energy consumption or their ability to pick up different shaped objects and place them in appropriately shaped holes? Or do they really care most about the appearance of their gait or whether their arm is drawn into flexion in front of their chest when they walk or run? These major goals may vary tremendously not only from patient to patient, but also may change for individual patients throughout life as they mature.

If we are unable to evaluate traditional, accepted modes of therapy, then how are we to assess new and innovative approaches, such as intrathecal baclofen for the ambulatory patient? Other new approaches may have major commercial implications and have led to the development of commercial treatment centers based on specific therapy systems and interventions, such as hyperbaric oxygen, casting and tone reducing orthoses, as well as physiotherapy 'systems'. Many of these 'innovative and alternative' approaches make promises to parents about the outcome of their children.

Thus, we have a daunting but essential job in front of us to base the therapeutic interventions we recommend and provide on sound scientific data. In order to achieve this, it will take a tremendous effort by people who are leaders in the field to develop funding sources, train professionals, and foster excellent clinical research in the area of CP.

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