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Understanding function and other outcomes in cerebral palsy

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Synopsis

Describing the status of children with CP and quantifying change in their status are two central challenges to research and clinical management of CP. The science of assessing and reporting status is outcome measurement and it is rapidly developing in the arena of CP. Due to the large number of domains to measure, the variability of CP manifestations, and a limited number of 'gold standard' evaluations, creating an accurate, comprehensive, responsive, and broadly applicable measurement strategy is a serious endeavor. Currently, a range of outcome measures are available to address CP issues across the spectrum of disability. The use of these measures, and others yet to be developed, will provide researchers and clinicians the best means to understand CP and the effects of treatments.

Keywords

cerebral palsy; outcome; clinical trials; function; disability

Care and research in childhood cerebral palsy (CP) is evolving. The process of change requires careful attention to understanding the status of children with CP – how and what they are doing, the things that are challenging, and the ways in which they adapt to their challenges. Outcome measurement is the way we describe the status of patients and research subjects. Outcomes are any of the things that can be measured and encompass all parameters of human existence from blood tests to walking speed to quality of life. The tools we use to measure outcomes may be laboratory tests, physical examinations, questionnaires, interviews, or any other evaluations. These tools may be called outcome measures, instruments, or assessments. In CP, outcome measurement is a prominent and important topic, especially because having robust means of measuring outcomes is vital to understanding the utility of treatments. If research cannot accurately measure the things that matter for children with CP, then it cannot establish if interventions are having useful effects. This chapter will address the challenges of outcome measurement in CP, the current status of outcome measurement in CP, and the issues of understanding change in childhood CP.

Measurement challenges with cerebral palsy

The measurement of outcomes in children with cerebral palsy presents an array of challenges. The issues of concern for children with CP are wide-ranging, chronic, difficult to quantify, resistant to change, and more reflective of disability than illness. These parameters lead to

frustration for the clinician or researcher who wishes to evaluate the status of a child or youth with CP.

CP impacts a breadth of arenas. As any person with CP, parent, or medical professional who cares for children with CP will attest, CP touches almost every aspect of life. CP causes changes in basic body functioning such as strength, coordination, and muscle tone. CP results in difficulty with functional tasks like walking, swallowing, accomplishing self-care, and communicating. In turn, these deficits contribute to decreased involvement in community, school, and family activities. CP has some impact on quality of life¹ and definitely creates additional stressors for caregivers²⁰. These facts illustrate the many potential problem areas to understand and to measure in CP. The sheer number of possible targets for measurement means that describing CP in a comprehensive and accurate fashion is hard to do.

Moreover, CP is a very diverse diagnosis with substantial variation in impairments and severity. Although CP may manifest with marked impairments and myriad secondary impacts, some individuals with CP have fairly modest disability and relatively few daily effects. Furthermore, CP is highly associated with other conditions including cognitive impairment and epilepsy that create their own issues. Because of the variability in symptoms, sequelae, and co-morbidities, any two children with CP may look very different. Understanding how those two different children are doing may mean using two entirely different evaluations that are targeted to the issues affecting each child. These differences create a need for flexibility in measurement strategies so as to address each child with CP in a meaningful fashion.

Another challenge is the long-term nature of CP. CP is not an acute illness. Children and youth with CP will always have CP, but their CP may impact them differently over time. It is of paramount importance to understand the long-term outcomes of CP and how interventions affect outcomes many years later. Studying outcomes in a longitudinal fashion over years, rather than weeks or months, is expensive, time-consuming, and messy due to the inability to control for extraneous factors. Nonetheless, longitudinal measurement is arguably the most important method to explore treatments and interventions for CP, as outcomes in adolescence and adulthood are of critical importance.

There are few gold standards or rubrics for measurement in CP. Many of the domains of concern are not easily quantified and there are no established benchmarks of measurement. For example, even in terms of walking, there is no single, best, and universally accepted method to measure how well a child with CP walks. Assessing things like quality of movement, happiness, ease of care, and independence is a confusing and frustrating venture. Unlike more quantifiable outcomes (blood pressure or birth weight, for example), most concerns in CP don't have an established 'ruler' to measure them.

One goal of outcome measurement is to assess changes that occur as a result of treatments or interventions. This is another concern in CP because so many of the available treatments do not seem to create big changes. With small treatment effects described for many interventions, at least with the available measurement tools, one question arises: are the available outcome measures really good enough? Either the measurement tools are not adequately sensitive to change and cannot detect meaningful effects of treatment or the treatments have insufficient effect to be meritorious. Until each individual outcome measure can be evaluated for its discriminatory properties and responsiveness to change, this conundrum will remain.

A final challenge in measurement in CP is the difficulty of looking at CP with a purely medical perspective. This perspective considers CP to be a disease and people with CP to be ill. It suggests that CP is something that has clear biological markers and that medical interventions can or should be employed to alter the underlying disease process. These ideas translate into a measurement paradigm that includes an assumption that the basic processes of CP should be

targeted with treatments and that improving the physiologic parameters of CP will result in improvements in the outcomes of interest. Generally, this is how things work for most health conditions. In the case of CP, however, this approach is not entirely satisfactory. First of all, many people with CP are not ill and are best described as having disability rather than poor health. When viewed as a chronic disability, CP is not something that is readily amenable to direct treatment. Furthermore, the degree of impairment in the more 'basic' issues of CP (like spasticity or strength) does not directly translate into functional (dis)abilities or more 'higher level' issues like quality of life. Thus, some of the usual assumptions about health-related outcome measurement are not fully applicable in CP. Understanding issues like change or the importance of individual preferences and goals in CP becomes even more salient when CP is viewed as a disability.

Current outcome assessment in cerebral palsy

In the last ten years, perspectives on outcome assessment in cerebral palsy have been influenced and shaped by the World Health Organization's International Classification of Functioning, Disability, and Health (ICF)³⁰ as a guiding principle. This seminal work describes and codifies a unifying means of understanding health status. The 2001 version for adults was followed in 2007 by an ICF for children and youth²⁹. The ICF is a framework that captures the breadth of issues created by CP and the many arenas of impact. In brief, the ICF considers that each person's function, disability, and health are interdependent and are modified by both environmental and personal factors. Thus, the ICF provides descriptions in three major domains of body function, body structure, and activities and participation (execution of tasks and activities and involvement in a life situation). These domains are further clarified with contextual factors, either personal or environmental. ICF domains have been used to understand and describe the many impacts of CP for individuals and allow for categorization of various CP outcome measures by the domain that is being assessed.

Use of the ICF in CP outcome measurement might best be understood with an example. Consider the use of botulinum toxin in a child with diparetic CP and an abnormal gait. A range of concepts across the ICF spectrum might be altered by use of botulinum toxin and each of these concepts could be assessed using different outcome measures or assessment tools. In the domain of body structure, botulinum toxin might have no effects, but it might change muscle structure or create cortical reorganization which could be detected with muscle biopsy or functional magnetic resonance imaging. In the domain of body function, changes in spasticity and strength could be measured with the Tardieu or Ashworth scales and dynamometry, for example. Activity and participation is a single domain, but may best be considered in two parts. Activity for a child with spastic diparesis might be altered with botulinum toxin by changing gross motor skills or gait pattern which could be assessed with the Gross Motor Function Measure²⁴, or an observational gait scale. Participation realms would include playing on a sports team or attending more social events, which might be measured with the Children's Assessment of Participation & Enjoyment¹⁴. Environmental contextual factors, unlikely to be changed by botulinum toxin treatment, would include things like accessible facilities and transportation to medical appointments. This example demonstrates the utility of the ICF in capturing the range of issues for children with CP.

The attention to these concepts has resulted in greater understanding of the relationships among the domains of the ICF in CP. Most notably, recent work has demonstrated that there are no fixed relationships among the domains of the ICF. Although improvement at the level of body function and activity may take place (for example, decreased spasticity and better gross motor function), this does not necessarily mean improved participation or family satisfaction³. Furthermore, severity of impairment or disability is not directly correlated with quality of life⁷. These findings have been best interpreted in the light of the ICF.

Choosing the most appropriate outcome measures or assessment tools in clinical research or the clinical care of CP is challenging. With a vast array of areas of interest, many tools have been developed and are being used. Many outcome measures in current use are fairly specific for one domain of the ICF, while others may span two or more domains. Some measures have been carefully designed, validated, and found to be reliable, whereas others were developed quite casually and have not been evaluated for their performance. Clinicians and researchers alike must think critically about the available tests, studies, questionnaires, evaluations, interviews, and technologies and they must consider the patient or subject, the situation, and the question at hand before making selections.

When considering outcome measures, it is necessary to evaluate the psychometric performance of each measure. The best measure is one that addresses the domain of concern, is validated and reliable, can be employed readily, and is responsive to change. For many measures, some of these criteria are not yet fulfilled. Validity and reliability are key concepts in outcome measurement that demonstrate the measure is truly assessing the concepts of interest and that the assessments are accurate and repeatable. Many measures in use for children with CP have been evaluated for validity and reliability in at least a preliminary fashion. Even so, caution must be paid to using each instrument in the manner it was intended, which means administering each measure precisely as the developers instruct, including avoiding the use of tool subscales if the subscales have not been demonstrated to stand alone, using the measure in intended populations, and administering the measure as recommended. Some measures are best described as classifications. For example, the Gross Motor Function Classification System (GMFCS) delineates five strata of motor functioning in children and youth with CP¹⁹. It is convenient and widely employed to describe severity of impairment in CP, but it has not demonstrated utility to detect changes over time or following interventions, nor was it designed for this purpose. The ability to pick up differences over time is called responsiveness or sensitivity to change. This concept is not well studied for most CP outcome measures. Some measures require special equipment, trained assessors, or lengthy periods of administration; these measures may be less attractive to use due to the costs or inconveniences associated with them.

An additional concern for choosing outcome measures in CP research is the need for appropriate study design. The desire for greater information about clinical prognosis, natural history, and effects of intervention is great and many researchers strive to provide answers. Unfortunately, if studies are not designed well, much effort and many resources may be expended without yielding useful evidence to advance knowledge. In CP research, many studies lack basic design elements such as defining a primary outcome measure (the main thing that the study intends to evaluate for change) or power calculations (to assure that the study has the right number of subjects to answer the research question). Many studies don't create high level evidence because they do not employ high quality design features, including randomization, blinding, allocation concealment, prospective recruitment, and adequate follow-up periods. Thus, without care in study design, the selection of the perfect outcome measure does not assure that a study is of value.

Examples of common outcome measures used in CP clinical care and research

Dozens of measures are used in the care and research of childhood CP. The items discussed below are some of the more common outcome measures and are provided as examples. This list is in no way exhaustive, nor should it be interpreted as a 'best available' list. A primary tenet of this article is the concept that outcome measurement in CP is complex and decisions about which assessments should be employed must be informed by the patient population and the goals of the evaluation. Measures will be reviewed based on the primary ICF domain they

address. Measures of body structure and function selected address the primary condition of CP and not secondary or associated conditions.

Body structure is not commonly evaluated in CP clinical trials. Although most children will have brain imaging to support their diagnoses of CP, subsequent evaluations are infrequent. In some settings, particularly for research, functional magnetic resonance imaging (fMRI) is employed. fMRI explores brain activity during functional tasks. Little is known about how fMRI findings relate to other outcomes or how to apply them clinically. Limited data have demonstrated reliability of fMRI findings in some populations^{4,13}. Due to the expense of fMRI and the need for specialty centers to perform it, this technology is not widely used at present.

Body function is a frequent arena for CP outcome measures. Spasticity treatments are common in CP care and various means of evaluation include the Ashworth and Tardieu scales. Scores using these scales are determined by physically moving joints and describing the ease and range of movement. The Ashworth and Modified Ashworth Scales have limited reliability and their validity is largely unproven (in part because spasticity has long been challenging to quantify)⁵. The Tardieu scale may be somewhat less unreliable¹¹. Despite the obvious shortcomings of these spasticity measures, they are almost universally used in clinical and research settings for CP, due to lack of better-performing assessments of spasticity that are easy to employ. Strength is often measured using dynamometry. Various dynamometers and techniques are available to directly measure force generation, and some are easier to use or are more reliable than others. In general, however, ratings for most muscle groups are reliable⁶. Strength measurement is used variably in therapy settings and for some research. Range of motion may be assessed with goniometry, using a hand-held device held alongside a child's limb to measure angles. Goniometry varies in reliability in research settings for children with CP^{9,26}, although it continues to be employed in clinical settings.

Activity measures are less frequently used in clinical settings, probably due to the time and training required for administration. The Gross Motor Function Measure is a therapist-administered battery of physical tasks that has established reliability and validity²³. It takes an hour to complete, but provides interval data quantifying a child's status that can be compared to motor development curves for CP²². The Pediatric Evaluation of Disability Inventory is a structured interview that generates scores in arenas of self-care, mobility, and social functioning¹⁰ with evidence of reliability, validity and responsiveness.

The Canadian Occupational Performance Measure may be assigned to the activity or participation domains. It assesses an individual's perspective on his or her tasks of daily life and leisure as well as the individual's satisfaction with his or her performance¹⁵. This measure is fairly unique because it creates individualized priorities rather than evaluating the very same tasks or actions for each participant. Reliability, validity, and responsiveness are established.

Most participation measures in use for children have adequate reliability and validity²⁵, with less demonstrated responsiveness. The Children's Assessment of Participation & Enjoyment examines what activities and interests a child is pursuing, as well as the child's enjoyment of the things she does¹⁴. This survey catalogues information about 55 activities including what, where, when, and how often in order to describe participation.

General health or health status measures include a number of questionnaires. Some are generic measures that are broadly applied to pediatric populations. These include the Pediatric Quality of Life Inventory²⁷, a questionnaire with physical and psychosocial subscales that may be completed by the child or a parent proxy. Another generic measure is the KIDSCREEN which addresses health-related quality of life with a questionnaire, again available for children or parents²¹. Among the disease-specific health status measures are the Cerebral Palsy Quality of Life Questionnaire for Children (CP-QOL)²⁸ and the Caregiver Priorities & Child Health

Index of Life with Disabilities (CPCHILD)¹⁷. The CP-QOL is a questionnaire, for parent or child completion, directed at quality of life in general rather than the more specific concept of health-related quality of life. The CPOCHILD measures health status and burden of care for children with severe impairments and is completed by the parent. All of these questionnaires have been evaluated for validity and reliability.

Lastly, classification measures have become common mechanisms for describing children with CP in the last several years. In lieu of anatomic descriptions of CP, such as spastic diplegia or total body involvement, researchers and clinicians have adopted function-based classifications. The most common schema is the GMFCS¹⁹. The GMFCS is reliable, stable, and easy to use, such that parents can accurately classify children with CP into the five strata of functioning¹⁸. The highest functioning stratum, I, includes children who walk without restrictions, but have limitations in advanced motor skills. The lowest stratum is V and includes children who have severely limited self-mobility, even with assistive technology¹⁹. Similar classification systems have been developed for manual abilities⁸ and communication¹².

Understanding change in cerebral palsy

Evaluating change is the primary reason to measure outcomes. Clinicians, researchers, and especially children and parents want to know if things are different. In CP, understanding change is a complex endeavor. Interventions for CP are not curative, at least with current medical science. This means that one must look for change in the symptoms or impacts of CP, but one does not expect dramatic resolution of CP or its associated disability. Assessing change in CP is evaluating much more subtle change than in some other diagnoses, such as having a lower blood pressure after taking medication, for example. As was reviewed above, most individuals with CP have multiple domains of concern that range across the ICF.

Even within any given domain, assessing change requires careful study. Children with CP are truly moving targets. Their function and well-being are expected to change as they grow, develop, and mature. Some of these changes are the result of typical development and may mirror typically developing children; other changes are a direct consequence of the impairments of CP. These changes are often described as the natural history of CP. As children with CP are expected to change, any change that is established over time may simply be the result of natural maturation or development. The pace and degree of change are generally not sufficiently understood such that highly reliable predictions can be made. Without this ability to prognosticate accurately, clinicians and researchers cannot establish if changes that follow a treatment for CP are the result of the treatment or are just 'natural history.' When working with populations of children with CP, studies that employ randomized designs control for this issue, but otherwise it is almost impossible to differentiate the effects of interventions from the effects of development in CP.

Another tension in defining change in CP is the issue of significance. Research may be conducted to evaluate an intervention and the results may indicate a statistical effect. This statistical effect would reflect a mathematical likelihood that change occurred with the intervention in terms of the outcome measurements. This mathematical happenstance, however, may or may not reflect a sufficient clinical change to justify the intervention. This concern is not frequent in CP research due to small sample sizes in most studies, but it remains salient. Consider a study that demonstrated a statistically significant improvement in knee-knee distance after botulinum toxin injection to the hip adductors¹⁶. The increase in knee separation was statistically analyzed and had changed from before to after, with an average increase of 10 centimeters. Some people would argue that increasing separation between knees by such a distance is not enough to make positioning, dressing, or diaper changes truly better.

This could be an example of a finding that is statistically significant but not clinically significant.

When measuring change, some sort of ruler must be used. In CP research, many different outcome measures are employed in this capacity. Most instruments have been evaluated to confirm that they truly measure what they are intended to measure and have established validity. Many of them, however, have not been evaluated for responsiveness. In an ideal setting, an outcome measure would be used in a population of subjects who are expected to show change to varying degrees. Additional means of evaluating change, maybe even a 'gold standard', would be used concurrently with the outcome measure and the data from each type of assessment would be compared. If the outcome measure scores changed in similar ways and with similar scope to the other assessments, then the outcome measure could be declared sensitive to change. Most measures used in CP have not been evaluated in this fashion. Thus, the numbers of outcome measures that have clearly demonstrated adequate responsiveness are low.

Tied to the idea of responsiveness is the concept of minimal clinically important differences (MCIDs). These differences are the amount a score on a measure needs to increase or decrease in order to reflect a change in status that is appreciable at a clinical level². The best way to define these differences is to follow individuals with repeated evaluations both with the measure that is being studied and with some other means of establishing if the individual has changed in a meaningful manner. Outcome measure scores from the subjects who experience minimal clinical changes are then used to calculate the MCID. When this calculation has been made and a meaningful change score is defined, it is easier to better design studies in terms of selecting sample sizes, because the power calculations are straightforward. Secondly, clinical care is better informed when change scores can be compared to established MCIDs. See Oeffinger, et al., (this issue), for studies to date to establish MCIDs using instruments in wide use for CP.

Conclusion

Outcome measurement may be the greatest hurdle in research and in the clinical management of CP. Fortunately, greater appreciation currently exists for the necessity of good outcome measures. With attention to the vast number of impacts of CP, the variability of CP manifestations, and the needs for valid, reliable, and responsive means of measuring the status of children with CP, more outcome measures are being investigated for their utility. The wise application of available outcome measures in optimized settings and thoughtful studies will lead to greater understanding of children with CP and the best management of their disabilities.

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