

ORIGINAL REPORT

DEVELOPMENT OF A FRAMEWORK TO DEFINE THE FUNCTIONAL GOALS AND OUTCOMES OF BOTULINUM TOXIN A SPASTICITY TREATMENT RELEVANT TO THE CHILD AND FAMILY LIVING WITH CEREBRAL PALSY USING THE INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY AND HEALTH FOR CHILDREN AND YOUTH

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Objective: To define a sub-set of functional goals and outcomes relevant to children and families living with cerebral palsy following treatment with botulinum toxin type A using the International Classification of Functioning, Disability and Health for Children and Youth.

Methods: We identified treatment goals and treatment outcomes from medical case records in 2102 assessments of 239 children with cerebral palsy treated with botulinum toxin between 1994 and 2009. Goals were set through assessment and discussion by experienced clinicians, therapists, parents and children.

Results: There were 61 separate goals, mapping to 40 categories, falling mostly within Body Functions: b710 *Mobility of joint functions* (414 times); b770 *Gait pattern functions* (374 times); b7351 *Tone of muscles of one limb* (117 times). A total of 93 separate treatment outcomes were identified, mapping to 51 categories. Two of the 3 most common outcomes correspond to the 2 most common goals (gait pattern and mobility of joint functions).

Conclusion: The International Classification of Functioning, Disability and Health for Children and Youth provides a useful framework to categorize the reasons for using botulinum toxin in children and focuses the clinical consultation not only on impairments but also functional outcomes.

Key words: ICF; functional goals; outcomes; classification; botulinum toxin type A; subset.

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INTRODUCTION

Cerebral palsy (CP) is the most common cause of severe disability in childhood (1) and the cause of more referrals to rehabilitation than any other diagnosis (2). A common clinical feature of CP is spasticity, which has a major impact on daily

personal activities and can restrict participation in social and educational programmes. Botulinum toxin type A (BoNT-A) is an effective treatment for spasticity (3, 4), and has functional benefits when combined with other rehabilitation treatments (5). It reduces spasticity by blocking the release of the neurotransmitter acetylcholine at the motor endplate (6). Although sprouting of the nerve to make new connections overcomes the effects of BoNT-A over a period of 4–6 months, there is a substantial window of opportunity for orthoses and therapy to address specific pre-determined goals of rehabilitation. BoNT-A has been demonstrated to show improvements in functional goals over and above those in a non-BoNT-A treatment group (5). Functional goals included catching a ball, maintaining a grasp on a scooter or cycle handle, activities involved with dressing, maintaining an eating utensil in the hand. In this paper, goals are defined as changes in impairment, activity limitation or participation restriction that are expected to be observed as a result of BoNT-A treatment. Outcomes are defined as those changes that were observed and recorded following treatment. Given the potential complexity of the benefits of botulinum toxin treatment, a system to capture these effects and provide a structure to the clinical consultation process would assist clinical decision-making and provide a formal method of involving parents and children in discussion about treatment objectives.

The International Classification of Functioning, Disability and Health for Children and Youth (ICF-CY) (7) provides the framework for facilitating accurate and effective communication, a common language for describing and classifying function and development in children and young people (8), both within the multidisciplinary team and for communication between regional health networks. The ICF-CY model describes functioning in two components: Body Functions and Structures, and Activities and Participation. Within these components, the ICF has more than 1,400 categories (8), making it somewhat impractical for day-to-day use. In recognition of this, the World Health Organization (WHO) has produced two generic ICF assessment tools (9), but even commonly used generic tools that are validated and reliable are not always appropriate for specific conditions, e.g. CP (10). This is being addressed by the WHO with the formulation of condition-specific Core Sets to facilitate

use of the ICF in clinical practice for a dozen common diseases (11). However, rehabilitation centres still find limitations when using the ICF in clinical settings (12). The proposed solution is the use of “subsets”, which are more appropriate for each setting (12). As part of a service evaluation, we undertook a retrospective review (over the last 15 years) of the Botulinum Clinic case notes of 239 children in order to identify and review the goals and benefits of botulinum treatment of spasticity in children with CP. These goals and benefits were formulated by both parents and the medical team. These goals and benefits were then described in terms of the ICF-CY categories. The aim of the review was to build on existing methods to develop ICF-CY subsets. We propose that the resulting set of ICF-CY categories provides an appropriate subset to categorize goals and outcomes associated with treatment of spasticity using BoNT-A in children with CP.

METHODS

In 1994, a botulinum toxin treatment regional service was set up in Yorkshire, UK. Children from hospitals throughout the north of England, an area which included up to 12 District and General Hospitals, attended the clinic through referral from local paediatricians, occupational therapists or physiotherapists. The multidisciplinary service consisted of paediatric neurologist, rehabilitation medicine physician, paediatric physiotherapist, nurse and occupational therapist. The goals and outcomes of treatment were therefore the result of a consultation by an experienced multidisciplinary team of specialists in neurological (re)habilitation. Importantly, children with CP and their parents/carers were also involved both in the formulation of treatment goals and in reporting the outcomes of treatment, defined here as parent-reported changes in activity, participation, body structure or function, at each hospital clinic attendance.

Children with a confirmed diagnosis of CP first treated with BoNT-A between 1994 and 2005 were included in the clinical service evaluation. Between 1994 and 2009, 239 children with CP referred for spasticity management received over 2000 clinical assessments, each undertaken with regard to botulinum toxin treatment. As part of a clinical service evaluation of the spasticity management clinic, a retrospective case note review was undertaken using a structured textual search. Data was recorded using a predefined proforma, which captured classification of CP, age, botulinum toxin treatment details (dose, frequency, muscles treated), goals statement, patient- and clinician-reported benefits. Goals for treatment and treatment benefits (outcomes) were recorded in the medical records during consultations with parents and children. Goals were documented as aims of treatment, and were repeated in a letter to both children’s GP and referring consultant after the clinic appointment. Outcomes were documented in the notes in follow-up clinics. All data was anonymised for coding and analysis. A standard method for coding the goals and benefits obtained from the medical records was used. The quality of the method was assessed in a pilot evaluation by the authors. Firstly, a sample of 10 medical records was examined and the goals and outcomes independently categorized by the authors into impairment (of Body Function and Structure), or function (Activity and Participation). These were mapped to the categories of the ICF-CY. Any differences were resolved through discussion. The pilot test highlighted no differences in the conceptual interpretation of the goals and outcomes into the ICF-CY categories. A full set of data from the rest of the medical notes was then extracted by a paediatric neurophysiotherapist. Frequency of goals and outcomes were presented using descriptive statistics. These were then further classified in terms of ICF-CY components and categories. A total of 239 children’s medical records were examined (Table I).

All data extraction from the medical records was undertaken by a single experienced paediatric neurophysiotherapist. Goals and treat-

ment outcomes were collated and defined by the appropriate category of the ICF-CY (7). The process was straightforward, but if there was any uncertainty or ambiguity linking the ICF-CY to the goals or benefits, these were noted and discussed amongst the authors. For example, the goal (and benefit) “Improve(d) application of ankle-foot orthoses” might have been defined as d540: Dressing, rather than e1151: Assistive products and technology for personal use in daily living. This example of “uncertainty or ambiguity” highlights the process. There were no goals or benefits of treatment that could not directly be linked to the ICF-CY. An example of goals and outcomes, and their corresponding ICF-CY (7) codes, are given in Table II.

As an example of the process, Improve Hand Function was described as a goal of treatment in the medical notes on 19 occasions, and Improved Hand Function was noted as a benefit of treatment on 15 occasions. This maps to the second-level ICF-CY domain d440 Fine Hand Use (d=Activities and Participation; Chapter 4 Mobility; d440 Fine Hand Use), defined by the ICF-CY as “Performing the coordinated actions of handling objects, picking up, manipulating and releasing them using one’s hand, fingers and thumb, such as required to lift coins off a table or turn a dial or knob. (Inclusions: picking up, grasping, manipulating and releasing; Exclusion: lifting and carrying objects) (7). Because the ICF-CY tree branches to deeper levels in different domains, dividing some categories into more component parts and defining these activities in greater detail, some goals and outcomes were defined at greater levels. The example above was at the second level, but the goal of treatment “Maintain gastrocnemius muscle

Table I. Classification of children with cerebral palsy (CP) at initial botulinum toxin treatment episode

Variables	
Children, <i>n</i>	
Total number of children	239
Male/Female	134/105
Age, years	
Youngest age receiving botulinum treatment	1
Oldest age receiving botulinum treatment	19
Age at first treatment, mean/median/mode	5 / 5 / 3
Age at last treatment, mean/median/mode	8 / 7 / 7
GMFCS, <i>n</i>	
GMFCS I	33
GMFCS II	61
GMFCS III	39
GMFCS IV	38
GMFCS V	10
Not GMFCS classified	58
CP classification, <i>n</i>	
Spastic diplegia	121
Hemiplegia	51
Quadriplegia	55
Monoplegia	1
Unclassified	11
Clinics and treatments	
Total number of assessments	2,102
Total number of injections	1,849
Lower limb injections/upper limb injections, <i>n</i>	1,752/97
Gastrocnemius, <i>n</i>	909
Hamstrings, <i>n</i>	331
Adductors, <i>n</i>	279
Biceps, <i>n</i>	29
Thenar eminence, <i>n</i>	25
Brachio-radialis, <i>n</i>	22
Treatment length, weeks, mean (min–max)	66 (1–536)
Injections received, <i>n</i> , mean (max)	8 (36)
Most clinics attended by child, <i>n</i>	13
Mean number of clinics attended	4

GMFCS: Gross Motor Function Classification System.

Table II. Example of goals and outcomes generated for one child: a girl aged 3 years 11 months at first injection clinic, treated over a period of 1 year 8 months at a total of 3 separate clinics

Goals of treatment		Outcomes of treatment		
Goals	ICF-CY domains and categories	Parent-reported outcomes of treatment	Clinically assessed outcomes of treatment	ICF-CY domains and categories
Improve cosmetic appearance	b180 Experience of self and time functions		Cosmetically improved	b180 Experience of self and time functions
Reduce spasticity	b7351 Tone of muscles of one limb		Improved passive range of movement	b7100 Mobility of a single joint of movement
Improve hand function	d440 Fine hand use		Grips objects better	d4401 Grasping
Prevent abnormal hand posture	b710 Mobility of joint functions			
Improve application of orthoses	e1151 Assistive products and technology for personal use in daily living	Improved social confidence		b1266 Confidence

ICF-CY: International Classification of Functioning, Disability and Health for Children and Youth.

length” navigates to the 4th level s75012 Muscles of the lower leg. Thus, the level to which the goals and outcomes are described is not defined by the study methodology but by the ICF-CY.

RESULTS

The sample appeared to be broadly representative of the general population, although there was a larger than normal proportion of children with only the lower limbs affected. The ratio of boys to girls was 1.28, which is comparable to the population ratio in Europe of 1.33 (13). The proportion of diplegic children was 49.8% compared with 13–25%, but proportions were similar in children with hemiplegia (21.3% compared with 21–40%) or involvement of all 4 limbs (23% compared with 20–43%) (2).

Sixty-one goals of treatment mapped to 40 categories of the ICF. For example, the goals “Keep up with peers” and “Reduce falls” both mapped to d450 Walking (Activities and Participation). Table III shows the ICF codes and categories, and the number of times they were identified as goals, for all 239 children. The most common ICF-classified goal was Mobility of Joint Functions, ICF Code b710 (414/2102 clinical assessments). The most common outcome was Gait Pattern functions b770 (285/2102 assessments – the second most common goal). Ninety-three outcomes of treatment mapped to 51 categories, of which 34 were common categories with the goals. These common goals are shown in Table III, along with the number of times they were reported as benefits or outcomes of treatment. Table IV lists the 17 remaining outcomes mapped to ICF categories.

DISCUSSION

This paper uses the ICF-CY to define a comprehensive subset of functional goals and outcomes for the treatment of spasticity in children with CP using BoNT-A. No ICF Comprehensive Core Set currently exists for children with CP, and we do not propose that our method sets out to address this, but we believe that this framework of ICF-CY categories forms the first defined subset of the ICF-CY appropriate for use in a specific

clinical setting, as proposed by Huber et al. (12). It serves as a guide for documenting changes at impairment and functional levels, and as a communication aid for referral and assessment. The approach for developing this subset from the ICF-CY differs from the construction of Core Sets commissioned by the WHO (11). The methods used to develop these Core Sets involved: a Delphi exercise (expert view); a systematic review of randomized trials to find the views of researchers; empirical data collection using the ICF checklist to identify the common patient problems of chronic conditions (11); and the gathering of up to 36 international experts for training in the ICF before undertaking the development of the Core Sets under supervision and guidance of the ICF Research Group (14). The process took place at 3 conferences organized over 13 months, and produced Core Sets for 12 chronic conditions.

Two types of Core Sets for each condition, *Brief* and *Comprehensive*, are described: the first for use in multidisciplinary assessment and the second for use in assessment of participants in a clinical study.

The Comprehensive Core Set for a specific condition “is a list of ICF categories that includes as few categories as possible to be practical, but as many as necessary to be sufficiently comprehensive to describe in a comprehensive, multidisciplinary assessment the typical spectrum of problems in functioning of patients with a specific condition” (11). The use of the ICF is gaining recognition in rehabilitation centres across Europe and beyond, and other methods to interpret goals and benefits using the ICF have been described recently (15–17). The approach we have used to develop a subset of the ICF-CY for children with CP focuses on goals for targeting spasticity using a specific intervention, and includes established outcomes of the intervention. The benefit of this approach is use of directly reported patient/parent goals and outcomes of the clinical treatment in a specific clinical setting and patient group in clinical consultation. This approach may be more practical than those acknowledged in terms of time and human resources, as this method involved a single research physiotherapist who collated and organized the data in approximately 100 days. We believe the specific intervention in a defined patient population provides a

Table III. International Classification of Functioning, Disability and Health (ICF) categories identified as treatment goals in 239 children with cerebral palsy

Code				Number of times as a goal	Number of times as an outcome
2 nd level	3 rd level	4 th level	ICF category title		
<i>ICF categories of the component Body Structures identified as treatment goals in 239 children with cerebral palsy treated with botulinum toxin</i>					
		s75000	Bones of thigh	3	0
		s75012	Muscles of lower leg	5	0
<i>ICF categories of the component Body Functions identified as treatment goals in 239 children with cerebral palsy treated with botulinum</i>					
b180			Experience of self and time functions	8	5
b280			Sensation of pain	1	2
	b2801		Pain in body part	18	7
b455			Exercise tolerance functions	8	23
b710			Mobility of joint functions	414	88
	b7100		Mobility of a single joint	9	69
	b7101		Mobility of several joints	82	44
b715			Stability of joint functions	5	0
	b7350		Tone of isolated muscles and muscle groups	9	7
	b7351		Tone of muscles of one limb	117	42
	b7353		Tone of muscles of lower half of body	46	11
b750			Motor reflex functions	1	0
b755			Involuntary movement reaction functions	15	52
b760			Control of voluntary movement functions	15	11
b765			Involuntary movement functions	14	13
b770			Gait pattern functions	374	285
<i>ICF categories of the component Activities and Participation identified as treatment goals in 239 children with cerebral palsy treated with botulinum</i>					
d340			Producing messages in formal sign language	3	1
	d4104		Standing	109	113
d415			Maintaining a body position	34	25
	d4153		Maintaining a sitting position	22	33
d440			Fine hand use	19	16
	d4401		Grasping	1	3
	d4452		Reaching	7	1
d450			Walking	56	69
d450-d469			Walking and moving	2	5
	d4551		Climbing	1	10
d460			Moving around in different locations	15	34
d465			Moving around using equipment	85	51
d510			Washing oneself	15	13
d530			Toileting	15	8
d540			Dressing	4	1
	d5700		Ensuring one's physical comfort	20	0
d599			Self-care, unspecified	10	3
d630-d649			Household tasks	6	0
<i>ICF categories of Environmental Factors identified as treatment goals in 239 children with cerebral palsy treated with botulinum</i>					
e310			Support and Relationships (Immediate family)	3	11
e580			Health services, systems and policies	7	34
	e5800		Health services	10	1
	e1151		Assistive products and technology for personal use in daily living	63	69

focus for the reporting of goals and outcomes in consultation with clinical specialists. We propose that this, combined with the patient-reported goals and benefits, increases the specificity of the subset for use in this clinical setting.

There are some limitations of using this approach. First of all, data was extracted from medical records by a single researcher. A second researcher would improve the validity of the subset, as linking the recorded goals and outcomes in medical notes to the ICF-CY categories is prone to the individual researcher's interpretation. There is also the question of the single-site sample on which the data was drawn. There is the potential for bias in the recording of information within medical notes, as well as

potential for incomplete record of the clinical consultation, as indicated perhaps by the 6 goals of treatment (Table II), which were not reported as an outcome of treatment. There is inherent bias involved in any data extraction. A further potential for bias in this ICF-CY classifications subset is that, during the early years of the service, referrals and treatment interventions focussed predominantly on lower limb spasticity: there were 100 botulinum treatments injections to the upper limb compared with 1749 injections to the lower limb.

Children and their families express needs in terms of the goals to be achieved, and clinicians discuss and add to these goals following a clinical assessment. The medical records of 239 children

Table IV. Additional International Classification of Functioning, Disability and Health (ICF) categories identified as Outcomes of Treatment in 239 children with cerebral palsy

ICF component	ICF Code		ICF domain/category	Times reported
	2 nd level	3 rd level		
Body functions		b1266	Confidence	19
Body functions		b4550	General physical endurance	1
Body functions		b4552	Fatiguability	7
Body functions		b7102	Mobility of joints generalized	3
Body functions		b7303	Power of muscles in lower half of the body	2
Body functions		b7800	Sensation of muscle stiffness	2
Activities & Participation		d4103	Sitting	1
Activities & Participation		d4208	Transferring oneself, other specified	1
Activities & Participation	d435		Moving objects with lower extremities	2
Activities & Participation		d4402	Manipulating	2
Activities & Participation		d4408	Fine hand use, other specified	2
Activities & Participation		d4552	Running	12
Activities & Participation		d4554	Swimming	2
Activities & Participation		d4750	Driving human-powered transportation	7
Activities & Participation		d8201	Maintaining educational programme	2
Activities & Participation	d880		Engagement in play	5
Activities & Participation		d9201	Sports	14

A summary of an ICF-based conceptualizing of the potential clinical impact of botulinum toxin in children with cerebral palsy is given in Fig. 1. We have illustrated this using the most common International Classification of Functioning, Disability and Health for Children and Youth (ICF-CY) categories identified as goals and benefits combined.

with CP, first treated with BoNT-A over an 11-year period, were reviewed and the goals and treatment outcomes collated and indexed to categories of the ICF-CY. A total of 57 ICF-CY categories describe these goals and benefits of treatment, of which 34 were common to goals and benefits. The sample is broadly representative of the general population in terms of distribution of limb involvement: only diplegic children are over-represented, and this is likely to be a result of the focus on treatment of spasticity of the lower limb during the early years of the clinic.

Goals and benefits from the clinics are classified under a total of 57 ICF Domains. The service evaluation identified 17 ICF-CY categories describing benefits of treatment that had never been defined as a goal of treatment, and stresses the importance of parents in reporting outcomes of treatment. For example: 3 children found it easier to ride their bicycles, and 4 were able to ride for the first time (d4750 Driving human-powered transportation); 2 children were able to participate more in school activities (d8201 Maintaining an educational programme); 5 children reported that it was easier to play games (d880 Engagement in play). One might consider these to be rather ambitious goals of treatment, but they are clearly potential outcomes in the treatment of children with CP that should not be overlooked in the assessment of more able children. On the other hand, 6 ICF-CY categories describing goals of treatment were not identified as outcomes. This may indicate that the treatment was unsuccessful, or the goals were not appropriate, but may suggest that the medical notes are not always comprehensive. Given the retrospective nature of this study it was not possible to use ICF qualifiers or facilitators to evaluate changes in functional states, as their scales are not sensitive for such purposes (12).

The subset could further be divided up into motor ability using the Gross Motor Function Classification System (GMFCS), or alternatively, distribution of spasticity. Although the GMFCS was not used in any of the clinical notes it was possible to classify gross motor function using the GMFCS from information documented in the medical records in 75.7% of children (Table II).

Few domains were present from the Environment chapter; this may indicate that the broader aspects of the impact of mediators and moderators on the clinical benefit were not specifically recorded in the way defined by the ICF, which uses a graded system of whether the environmental factor acts as

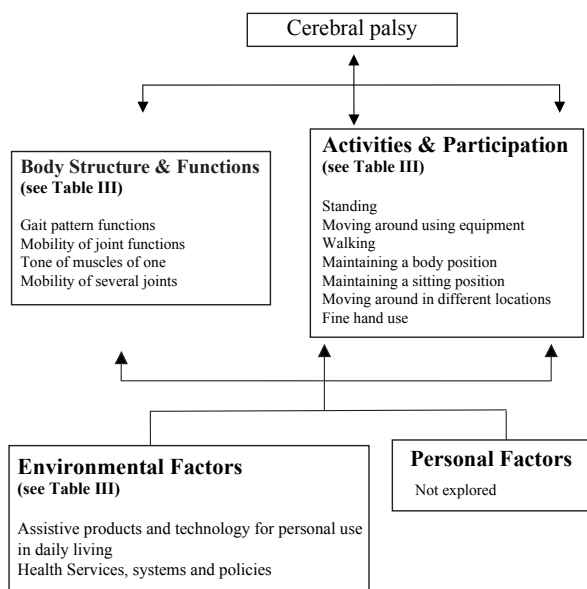


Fig. 1. International Classification of Functioning, Disability and Health (ICF) model conceptualizing botulinum toxin A treatment of children with cerebral palsy using the most common categories of goals and benefits of treatment in 239 children.

a barrier or a facilitator. The ICF conceptual framework and the use of this ICF-CY subset would aid in improving clinical consultations and medical record-keeping. At follow-up appointments, many families expressed concern about the timing and adequacy of their child's therapy programmes in relation to BoNT-A treatment: for example, the timing of orthotic appointments following treatment. We believe that using this subset of ICF-CY classifications as a standardized and consistent means of communication with local therapists will enhance the planning and delivery of therapy programmes. For example, the most common ICF-CY category from Environmental Factors (e1151 Assistive products and technology for personal use in daily living) describes the improvement in benefits and tolerance of orthotic devices.

Advantages of the proposed subset include improvement in goal-setting and communication within a clinical consultation, facilitation of coordination of therapy by different healthcare professionals, improved documentation of goals in medical records (18), and allowing the clinical consultation and treatment to focus on outcomes that are seen as important to children and their families. The use of a core data set based on ICF categories has the potential to encourage clinicians to seek goals for intervention in the activity and participation domains. This study shows that clinicians using rehabilitation/habilitation interventions will often conceptualize their interventions in the function domain, which is not necessarily the most meaningful on a day-to-day basis for a child with CP, whereas goals in the activity/participation domains are those that are most allied to developing independence and lead to consideration of environmental/person factors. A further possible use of this subset is to aid the construction of a Patient Reported Outcome Measure (PROM) (19, 20) for use within a clinical setting but also in the context of clinical trials.

In conclusion, this paper demonstrates that the goals and outcomes of treatment using BoNT-A in children with CP are readily described using the ICF-CY. We recommend the use of these categories both for improved communication between healthcare professionals and for formal clinical documentation. An important factor in the development of this ICF-CY subset is the inclusion of outcomes reported by parents following treatment; these illustrate that clinicians should also target Activity and Participation domains to establish goals that are more significant for the family. This approach can complement the existing approach of ICF-Core Set development by using patient- and clinician-generated information arising from "real life" clinical consultations.

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