

AACPDM Methodology to Develop Systematic Reviews of Treatment Interventions (Revision 1.1)

2004 Version

Inside

**The Step-by-Step Process for Authors Creating a AACPDM
Systematic Review**

**Approved by the Treatment Outcomes Committee
September 29, 2004**

The procedures in the first versions of this manual were authored by Charlene Butler in 1998-1999 and approved by the 1998-1999 AACPDM Treatment Outcomes Committee. Their purpose was to standardize the development and presentation of evidence tables and review articles about treatment outcomes for children and youth with developmental conditions.

The procedures in this updated “2004 Version” have been revised by the Treatment Outcomes Committee members named below, who formed a methodology subgroup. They have been reviewed by the full Treatment Outcomes Committee and were approved in principle at the September 2004 annual meeting of the AACPDM. This document replaces the original methodology document.

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INTRODUCTION

The AACPDM has undertaken the development of systematic reviews to summarize the literature about specific intervention strategies used to assist children with developmental disabilities. Systematic reviews do not specify how to treat a condition, *but rather* they gather and present the best evidence – for or against - the effectiveness of an intervention. These reviews are not “best practice” documents or practice guidelines. The goal of these reviews is to present the evidence about interventions in an organized fashion. Such reviews can assist to identify gaps in evidence, and can help identify new research that is needed. The Academy is neither endorsing nor disapproving of an intervention in these reviews.

This document describes the updated methodology for developing and presenting an AACPDM systematic review – a review that is based on a two-part conceptual framework. This framework:

- 1) analyzes and categorizes treatment outcomes from studies according to the components of the International Classification of Functioning, Disability and Health (ICF) (WHO, 2001), and
- 2) judges the strength of the evidence from each article according to the study design and the researchers’ rigor in the conduct of the study.

This original version of this methodology was based on the model of disablement described by the National Centre of Medical Rehabilitation Research (NCMRR) disablement classification and, the World Health Organization (WHO) ICIDH-2 model of disablement. When the 2001 version of the ICF was published, we adopted it as the classification system for these systematic reviews, replacing the NCMRR and ICIDH-2 classification systems. Readers are encouraged to visit the website of the World Health Organization (WHO) to gain more information about the structure and intent of ICF.

The methodology described here provides a road map for the essential steps in completing a review.

DEVELOPING A SYSTEMATIC REVIEW: STEP BY STEP

1. Define the population of interest.

Define the patient population as precisely as possible to focus the literature search to relevant studies. See Example 1 below.

2. Define the intervention as specifically as possible.

Specifically state the intervention that will be evaluated to focus the literature search to relevant studies. See Example 1 below.

Example 1: *Specifying the population and intervention addressed by a review. Populations specifically excluded must also be described.*

The intervention, *intrathecal baclofen*, includes baclofen administered by (1) single or multiple injections over the dorsal surface of the spinal cord) or (2) a subcutaneous implanted pump that delivers a continuous infusion into the lumbar cerebrospinal fluid. It excludes orally-administered baclofen.

This review is concerned with children and youth (birth to 19 years) with cerebral palsy. *Cerebral palsy* has traditionally been described as an evolving disorder of motor function secondary to a non-progressive pathology of the immature brain and is characterized by abnormalities of movement (i.e., spasticity, athetosis, chorea, dystonia, and ataxia). Two-thirds of individuals with cerebral palsy have spasticity, either alone or in combination with the other movement abnormalities. The review includes studies (1) whose subjects were primarily individuals diagnosed with cerebral palsy with spasticity, alone or in combination with other types of abnormal movement. This review excludes studies of spasticity of spinal origin (e.g., multiple sclerosis or spinal cord injury) or of cerebral origin due primarily to other causes such as traumatic brain injury.

Defining the population and intervention carefully is a crucial step as this will affect the generalizability of the review.

3. Create, execute and record search strategy

The comprehensive search for evidence is a key factor in a good systematic review. A comprehensive search of published literature **must** be undertaken. All published literature regarding the intervention and its application to the population of interest must be identified.

With today's comprehensive, complex electronic search mechanisms it is crucial that a search strategy be designed and recorded as part of this review process. It is highly recommended that this comprehensive search strategy be developed with the assistance of a health science librarian.

For these reviews, the literature search strategy is limited to published literature. Some systematic reviews include "grey literature" which is unpublished, non-journal sources such as results from dissertations or abstracts from scientific meetings that have not yet been published in paper format. While these can provide useful information, they are difficult to

find and have not necessarily been subjected to the same level of peer review as published literature. These unpublished, non-peer reviewed sources will **NOT** be included in the AACPD reviews. Only original, peer reviewed, literature published in a scientific journal is to be included.

When searching the published literature, identify key words or Medical Subject Headings (MeSH) to be used for your search that reflect your intervention and population already defined above. State the inclusion and exclusion criteria applied to the search and to the subsequent selection process.

Your search strategy, once developed, should be applied to electronic data bases which, given the nature of this field, should include MEDLINE and CINAHL. If the intervention is of an educational nature or educationally related outcomes are possible, ERIC should also be searched. Similarly, PsychInfo should be searched if psychological interventions or outcomes are of interest. EMBASE should be searched if it is available to authors. Authors are responsible for identifying appropriate databases and searching them.

It is also expected that authors will have reviewed the following sources to ensure that all relevant literature is included:

- Database of Reviews of Effectiveness (DARE): DARE summarizes reviews identified and appraised by National Health Service's Centre for Reviews and Dissemination at York in England.
- Cochrane Database of Systematic Reviews contains full text of systematic reviews completed by the Cochrane Collaboration, an international network committed to preparing and disseminating systematic reviews in health care
- The Physiotherapy Evidence Database (PEDro)

You may find that the following sites, as well as others, will assist you in developing a search strategy:

- Canadian Centres for Health Evidence (currently at www.cche.net)
- Best Evidence at www.acponline.com summarizes individual studies and systematic reviews from over 100 medical journals.

The search strategy must be recorded and reported in the published systematic review.

In addition, authors are expected to review the references of all retrieved articles for additional relevant literature.

For guidance with searching for literature, we recommend that you review one of the many current evidence based practice textbooks. Searching and search strategies are generally well described there. In addition, authors can contact the Treatment Outcomes Committee members for assistance and tips. If possible, you should also solicit the assistance of medical librarian.

While one author of the review may complete the search process (with the librarian), all authors of the study must feel comfortable that the search has been comprehensive and that all relevant literature has been identified.

All abstracts found in the search process are then retrieved. At least two authors must independently read the abstracts obtained by the search and independently decide if an abstract should be included in the review or not. If there is no abstract, the full paper must be retrieved and reviewed. If the abstract makes it difficult to determine if the paper meets the review criteria, the full paper must be retrieved. The authors of the review should then meet to discuss their decisions and reach consensus. They should document this process by keeping records of which studies were retrieved and which studies were excluded (along with the reasons for exclusion).

This review process is developed only for studies that report empirical data; studies using qualitative methodology cannot be rated by our methodology, even though they may provide important information. If they are retrieved in the search, they should be identified and included in the reference list. When reporting why articles were excluded, they should be identified and be noted to be qualitative rather than quantitative. The reader of the review will then be able to obtain the citations to these articles from the reference list.

Similarly, if single subject studies are found, they should be reviewed. They should be referenced and should be noted in Table III but will not be rated for level of evidence or quality of conduct. Our methodology does not currently allow us to adequately rate the level of evidence or quality of these studies. Work is currently being done by the Treatment Outcomes Committee regarding single subject design; however, at this time the above mentioned process will be used.

Example 3: *Specifying types of research examined and search process used.*

The literature search was limited to published studies, full-text available in English and included the following electronic databases: MEDLINE (1966 to December 2000), Cinahl (1982 to September 2001), EMBASE (1988 to September 2001), ERIC (1966 to October 2001). AMED (1985 to November 2001) and Psychinfo (1984 to October 2001). PEDro and DARE databases were also searched. The search term used was 'conductive education'. Reference lists in studies and review articles were also examined for appropriate articles.

Eighty-eight citations were examined, and 68 were excluded because they were commentaries or review articles rather than research. Of the remaining 20 articles, two were excluded because they evaluated children with diagnoses other than CP (ref). One other article was a survey of health professionals' knowledge of CE (ref). Another article (ref) reported the results of a program evaluation and the majority of outcome measures did not address changes in the child. Finally, another study (ref) used qualitative methods and thus did not fit into the methodology of this systematic review.

Fifteen articles met the inclusion criteria. Two of these articles (ref) were retrieved as reports on microfiche rather than published articles. They were included in the review because they met the inclusion criteria, and they were referenced in other articles

4. Extract data from each included study

At least two authors must participate in extraction of the data from the original papers that are to be included in the review. The extracted data is summarized by each author on a “Study Data Extraction Summary Form” (**Appendix One**).

The steps in this data extraction process for BOTH authors are:

1. Each of the two authors must independently read each included article.
2. Each will code the level of evidence based on the research design of the article. (described in **Appendix Two**)
3. Each will assess the quality of the study and assign a quality rating. (described in **Appendix Three**)
4. Each will extract subject and descriptive information relating to the definition of the population.
5. Each will document the specific of the nature of the intervention of interest, as well as noting any description of co-interventions that may have been in play.
6. Each will identify outcomes of interest and the measures used to assess them.
7. Each will code the ICF component represented for each outcome of interest. (described in **Appendix Four**)
8. Authors will then come together and come to consensus about each of the above facts.

The final summary sheets for each article must be retained by the reviewers in the event that a reader seeks clarification of information included in the review. It is important that all information is available for audit purposes.

5. Use extracted data to create summary “evidence” tables.

For each report, the following five tables will be completed and included in the paper. Table One and Table Two are standard tables which contain information about how the review was done and do not include your own data. Tables three, four and five will have standard format but will be completed using your own data, now found on your data extraction forms.

Table One: Classification of Outcomes table. This table will be the same in all reports, will be the standard outcomes table demonstrated in **Appendix Four**, used to orient the uninitiated reader of your article to the ICF components. For more information regarding the

WHO's ICF, reviewers should consult the WHO website and or obtain the WHO's textbook describing the classification system (International Classification of Functioning, Disability and Health, WHO, 2001)

Table Two: Levels of Evidence table: This table, the same in all reports, will be the standard Levels of Evidence table defined in **Appendix Two**.

Table Three: Participants and Interventions Summary Table. All included studies should be listed on this table in chronological order. An example of this table is found in **Appendix Five**

Table Four: Conduct of Study Table: An example of this table is found in **Appendix Five**. Only studies with levels I, II or III levels of evidence are included in this table.

Table Five: Outcomes, Measures and Results Table: An example of this table is found in **Appendix Five**. Only studies with levels I, II or III levels of evidence are included in this table.

6. Write the review article being sure to answer the following questions.

1. What evidence exists about the effects of the intervention in the components of ICF? in which it was expected to work?
2. What evidence exists about the effects of the intervention in the other components of ICF?
3. What evidence exists for linkages of effects within and between these components (i.e, which effects, if any, appear to carry over automatically?)
4. What kinds and magnitude of complications have been documented?

An understanding of the medical risks is necessary for assessing whether the benefits of an intervention outweigh its risks. The review will report the type and severity of complications that have been documented. It will not express a judgment about whether an intervention does more good than harm because a benefit/harm analysis can more appropriately be made by the reader who is considering the intervention for a particular individual.

5. What is the strength of the evidence?

Is the evidence worthwhile, clinically speaking? Is it statistically valid? With what level of confidence can the observed results be attributed to the intervention? This discussion should be based on the level of evidence of the found studies but also the quality of these studies.

Include in this discussion, comments on statistical significance of results, clinical significance of results and notation of evidence consistently replicated in several higher quality studies. Reference the specific of the population and the intervention and make comment on the generalizability of the evidence. In the discussion, any interesting or important findings from lower level studies or single subject design studies can be included.

7. Submit the article to the Treatment Outcomes Committee for publication under the imprimatur of the AACPDM.

In order for a review using this methodology to be published in Developmental Medicine and Child Neurology under the imprimatur of the AACPDM, the Treatment Outcomes Committee must review the article.

The involvement of the committee should **NOT** begin AFTER your review has been completed.

When you have an idea for a systematic review and wish to explore it or know that you would like to proceed, please contact the Treatment Outcomes Committee Chair. S/he will document your name and that of your co-author/s, as these reviews require at least two authors/reviewers. The title and topic of your review will be requested. This is to ensure that no others currently have the same review under way. This process also protects you in the process so that if others, after you, come wishing to review the same topic you will have that topic already identified for your authorship.

You can then proceed to complete the review on your own, or, if you would like assistance methodologically, TOC members would be happy to help you. They can be contacted through the chair of the committee.

When you have completed your review, your manuscript is submitted to the TOC chair. It will then be reviewed by five past or current members of the TOC including a minimum of 3 active TOC members. Comments will be provided. The role of the committee is to serve in a reviewer capacity and to ensure the review has followed the methodology outlined here.

When the TOC reviewers feels that the review can be signed off and you, as authors, are happy with the review, the Chair will forward the review to the President of the AACPDM who reviews it prior to it being forwarded to the DMCN with the committees' approval. The goal is that this process then leads to an expedited review process for the paper at DMCN.

Throughout this process, the TOC members are there to help you. At any stage please feel free to contact your TOC chair who will assist you or direct you to others who can assist.

Study Data Extraction Summary Form

Reviewer's Name:

Citation information:

1. Level of Evidence

Research Design:

Level of Evidence (based on that design):

2. Quality of the Study

Quality rating

3. Descriptive Information about the Study

Practice setting: (Place and/or type):

Population/Subjects:

Population Description: (diagnosis, diagnostic subgroups if relevant, ages severity, similarities between treatment and control groups if relevant etc)

Number: In treatment group:

In control group:

Specific intervention used: (nature, duration, dose if relevant)

Description of control state (if used):

Complications noted:

AACPDM SYSTEMATIC REVIEW OF THE EVIDENCE
 APPENDIX ONE: STUDY DATA EXTRACTION SUMMARY FORM

4. Outcomes

Treatment compared to another condition (no treatment, placebo, or alternative treatment)

<i>Outcome of Interest</i>	<i>Measure Used to Assess*</i>	<i>ICF Component</i>	<i>Stats</i>

Legend:

ICF Component Component of ICF represented by measure and outcome of interest (record after completing Step 6).

Stats Report results using the following three abbreviations:
ss: Statistically significant. Record the 'p' value. If there are two groups, record if the results favored the intervention or the control group
ns: No statistical significance
nr: Statistics not reported empirically

CODING LEVELS OF EVIDENCE

There are numerous systems in the literature and developed by organizations interested in reviewing the quality of evidence for grading the “level of evidence.”. This grading is the most important step in determining the quality of the study.

The classification that the AACPDM reviews has been based on the work of Dr. David Sackett, first with the Canadian Task Force on the Periodic Health Examination. First published in 1980, the grading system was for many years referred to as "Sackett's levels of evidence and grades of recommendation". The classification was republished with little change in 1993, but more recently has evolved further and changed under the auspices of the NHS Research and Development Centre for Evidence Based Medicine (CEBM) in Oxford, England. The current version developed by Sackett (then Director of CEBM) and his colleagues was posted on the CEBM web site on the Internet at www.cebm.net in 1998.

This hierarchy of “levels of evidence” is based on research design types. The design quality of qualitative research and single subject design cannot be assessed appropriately using this hierarchical system. At this time, while specific attention is paid to developing fair and appropriate assessment criteria for qualitative and single-subject research, these study types are not included in the AACPDM reviews.

The following table, **which will be called “Table Two – Levels of Evidence” in your review**, shows the classification of levels of evidence that the AACPDM uses in its reviews. In descending order, the designs are decreasingly able to demonstrate that the intervention—and not something else—was responsible for the observed outcome. Level I evidence is the most definitive for establishing causality, with greatest reduction in bias. Level IV can only hint at it; Level V only suggests the possibility.

Level	<i>Intervention (Group) studies</i>
I	Systematic Review of randomized controlled trials (RCT's) Large RCT (with narrow confidence intervals) (n >100)
II	Smaller RCT's (with wider confidence intervals) (N<100) Systematic Reviews of cohort studies “Outcomes research” (very large ecologic studies)
III	Cohort studies(must have concurrent control group) Systematic Reviews of Case Control Studies
IV	Case series Cohort study without concurrent control group (e.g. with historical control group) Case-control Study
V	Expert Opinion Case Study or report Bench research Expert opinion based on theory or physiologic research Common sense/anecdotes

AACPDM SYSTEMATIC REVIEW OF THE EVIDENCE APPENDIX TWO: CODING LEVELS OF EVIDENCE

This table is based on the 1998 revision of the Centre for Evidence-based Medicine Levels of Evidence ([www. cebm.net](http://www.cebm.net)) and remains the most recent revision. Go to their website as noted, click on “toolbox” and go to “levels of evidence” for more details with respect to the levels and the definitions associated in this table.

Authors of an AACPDM review should consult a general clinical epidemiology textbook prior to beginning this process and undertaking their review to ensure that they are classifying studies appropriately.

A word of caution and example of error in study classification: In the developmental field, there are many studies which involves a group of patients being selected, being measured for a given outcome or state, the being provided with an intervention and being measured again. This has risk of being classified erroneously as a “case control study in which the cases acted as their own controls”. This would indeed be erroneous use of the epidemiologic term case control study and in fact, this study would be a case series. A case-control study involves identifying a group of individuals *with* a given state/poor outcome (cases) and a group *without* the given state/good outcome (controls) and then looking back historically to identify whether or not both groups were equally exposed to the intervention of interest (the exposure). This is one example of a pitfall in assigning level of evidence is noted here, because of its common nature and to serve as an example, demonstrating the need to understand study design prior to undertaking the review process.

How are these levels used in the reviews once they are determined? All studies are referenced in your Table Three of reviews; however, only studies which are found to be representative of Levels I, II or III evidence will have further data referenced in your Tables IV and V of the review.

ASSESSING QUALITY OF CONDUCT OF A STUDY

Assessing the quality of an intervention study involves a number of steps. The first, and most important step is the assessment of the strength of the study design. This is completed through the assessment of the “level of evidence” demonstrated in the study. This process is outlined in Appendix Two: “Coding Levels of Evidence”.

Over the past number of years, it has been noted by those interested in the methodology of systematic reviews that even if a study is thought to be strong based on study design (level of evidence) it may still have problems which limit its quality. For this reason, researchers have developed “conduct” questions which can be used to rate study quality in addition to the use of design.

The AACPDm Treatment Outcomes Committee agrees that this is an important step. A subgroup of the 2003/2004 committee (O’Donnell, Darrah, Adams, Roxborough and Damiano) reviewed the literature regarding conduct/quality scoring systems and adapted those systems to create the following scoring system for AACPDm reviews.

Quality assessment only needs to be completed on those studies which are Levels I, II or III.

In this system, the conduct of an individual study will be judged as Strong (‘yes’ score on 7 or 6), Moderate (score 5 or 4), or Weak (score ≤ 3).

The questions are as follows:

1. Were inclusion and exclusion criteria of the study population well described and followed?
2. Was the intervention well described and was there adherence to the intervention assignment? (for 2-group designs, was the control exposure also well described?)
3. Were the measures used clearly described, valid and reliable for measuring the outcomes of interest?
4. Was the outcome assessor unaware of the intervention status of the participants (i.e. were there blind assessments)?
5. Did the authors conduct and report appropriate statistical evaluation including power calculations?
6. Were dropout/loss to follow-up reported and less than 20%? For 2-group designs, was dropout balanced?
7. Considering the potential within the study design, were appropriate methods for controlling confounding variables and limiting potential biases used?

The answer to each of these questions must be recorded for each study and will be displayed on Table IVa of your review.

AACPDM SYSTEMATIC REVIEWS OF THE EVIDENCE
APPENDIX THREE: ASSESSING QUALITY OF CONDUCT OF A STUDY

If your review of the literature includes a systematic review, evaluate the conduct of the review using the questions below. These questions have been taken from an article that reviewed the validity of this index (Oxman and Guyatt, 1991). Complete Table IVb. There is no classification of the conduct score.

The questions are as follows:

1. Were the search methods reported?
2. Was the search comprehensive?
3. Were the inclusion criteria reported?
4. Was selection bias avoided?
5. Were the validity criteria reported?
6. Was validity assessed properly?
7. Were the methods used to combine studies reported?
8. Were the findings combined appropriately?
9. Were the conclusions supported by the reported data?
10. What was the overall scientific quality of the overview?

If you require assistance in using this conduct rating, please refer to the reference below, or contact a member of the Treatment Outcomes Committee.

Oxman, A. D. and Guyatt, G. H. (1991). Validation of an index of the quality of review articles. *Journal of Clinical Epidemiology*, **44**, 1271-1278.

CODING OUTCOMES BY ICF COMPONENT

BACKGROUND

The AACPDMD coding system has changed from use of the combined NCMRR/WHO (beta version of ICF) dimensions-of-disability classification to use of the WHO International Classification of Functioning, Disability and Health (ICF), published September 2001. This version has been accepted by 191 countries as the international standard to describe and measure health and disability.

All new evidence reports will use this classification. Earlier reports published or under review by the committee will use the earlier classification shown in the original methodology. (Please see the AACPDMD website to find a copy of the previous iteration of the methodology).

The ICF has *two parts*, each with *two components*. Each component can be described in positive or negative terms if a deficit is present.

Part 1: Functioning and Disability

- (a) Body Structure and Functions (negative term = impairment)
- (b) Activities and Participation (negative terms = activity limitation and participation restriction)

Part 2: Contextual Factors

- (a) Environmental Factors (either facilitators or barriers)
- (b) Personal Factors

FUNCTIONING AND DISABILITY:

Body Structures are anatomical parts of the body such as organs, limbs and their components. Impairments are problems in body structure as a result of deviation or loss. Structures include structures of the nervous system, the eye, structure involve in voice and speech structure of the cardiovascular system, immunologic and respiratory systems, structure related to digestive, metabolic and endocrine systems, structure related to genitourinary and reproductive systems, structure related to movement and skin related structure.

Body Functions are the physiologic functions of body systems (including psychological functions). Impairments are problems in body function as a result of deviation or loss. This component includes mental functions (e.g. intellect, temperament), sensory functions (e.g. visual acuity, balance, pain), functions of the cardiovascular system, haematological, immunological and respiratory systems (e.g. heart rate, general physical endurance), function of the digestive, metabolic and endocrine systems (e.g. swallowing), function of the genitourinary and reproductive system (e.g. urinary incontinence) and neuromusculoskeletal and movement-related functions (e.g. range of motion, muscle strength)

Activity is the execution of a task or action by an individual. Participation is involvement in a life situation. Activity limitations are difficulties an individual may have in executing activities. Participation restrictions are problems an individual may experience in involvement in life situations. WHO provides four different alternatives for coding activity and participation domains, ranging from using them interchangeably for all activities to having them represent mutually exclusive activities. For our purposes, we have chosen to have total overlap of domains for the two definitions. That is, when classifying outcome of a study, activity and participation outcomes will be identified in one heading “activities and participation”.

CONTEXTUAL FACTORS

Environmental factors make up the physical, social and attitudinal environment in which people live and conduct their lives. They can be viewed as facilitators (positive influence) or barriers (negative influence).

Personal factors are the particular background of an individual’s life and living and compromise features of the individual that are not part of a health condition. These factors may include gender, race, age and other health conditions. These are not well development to date in the ICF manual and must be used with caution, to ensure they are not better classified under body structure or body function.

STICKY WICKETS IN CODING

To develop the systematic review evidence tables, we identify and code the measures found in the review of each research studies. Each measure will be coded as to whether it represents an outcome in the body structure, body function, activity/participation or contextual factors components.

If you are unclear as to how to classify a measure, look carefully at the items of the measure. For example, some believe that quality of life measures are at the level of participation; however, they too must be reviewed as the component items may in fact be at a body structure, function or activity level. A scale or outcome measure should be reviewed for content and coded based on the majority of items. Subscales of a measure may represent different ICF components; however, these should be differently codes ONLY if the developers of the scale have demonstrated the reliability and validity of the sub-scales of the scale as stand-alone items.

WHERE WILL THIS INFORMATION BE RECORDED?

Every review will reinforce this system of coding outcome by having a table, which will be labeled “Table One” which will identical in every review. That Table one will be as follows:

Table One: ICF Components and Definitions

AACPDM SYSTEMATIC REVIEW OF THE EVIDENCE
APPENDIX FOUR: CODING OUTCOMES BY ICF COMPONENT

ICF Component	Definition
Body Function	Body functions are the physiological functions of body systems include psychological functions
Body Structure	Body Structures are anatomical parts of the body such as organs, limbs and their components
Activity	Activity is the execution of a task or action by an individual
Participation	Participation is involvement in a life situation
Context/Environmental Factors	Environmental factors make up the physical, social and attitudinal environment in which people live and conduct their lives

In addition, the data extracted related to the outcome measures is recorded on the data extraction summary sheet and will later become part of Table V of your review and will reference these components. Remember, only studies with Level I, II and III evidence are included in Table V. For systematic review articles, only the primary outcomes extracted from the compilation of studies should be reported.

SUMMARY

The ICF classification system represents a common language for rehabilitation disciplines to use to describe the level of client goals, intervention or outcome. For our purpose here, we are using it to code treatment outcome from studies of interventions in order to aggregate otherwise disparate research results into categories to help us make sense of bodies of evidence.

A complete description of these ICF components is found in the WHO publication from 2001 outlining the system. This is found and referenced at the WHO website found at www.WHO.org

Summary tables - Examples

INTERVENTIONS AND PARTICIPANTS

Table III summarizes the interventions and participants in the 15 studies included in the review.

Table III: Summary of studies – interventions and participants

Study	Level of evidence	<i>CE intervention</i>	<i>Control Intervention</i>	<i>Population</i>	<i>Total n</i>	<i>Ages</i>
Research design						
1972a Heal ¹⁸	II-W (2/7) Cohort study with concurrent control group	CE by 2-4 professionally trained ‘therapist-teachers’ and institutional aides in a residential school; 13 1/2 hr/day Duration: 12 months	3 training programs in orthopedic residential schools Duration: 12 months	CP, non-ambulatory, IQ<70, able to understand simple instructions Children in treatment and control groups matched on mental age, chronological age, type of CP and motor ability	25 CE=10 Ctl=15	5-13 y
1972b Heal ¹⁹	IV-W (0/7) Descriptive case series	CE by conductors at Peto Institute in Budapest; Discharged between 1950-1965 Duration: >1 mo, range unknown	None	866 (626 with CP) {ataxia (28), diplegia (219), hemiplegia (137), double hemiplegia (29), athetosis(213)}	626 ^a	Not given
1973 Clarke ¹⁵	IV-W (2/7) Case series without controls	Rhythmical Intention (not specified by whom) at the Spastic	None	Athetosis CP, average intelligence	6	6 1/2 – 7 1/2 y

AACPDM SYSTEMATIC REVIEWS OF EVIDENCE
 EXAMPLES OF SUMMARY TABLES III,IV, AND V

1974 Cotton ¹⁷	V Descriptive case series	Centre; 5 mornings/wk Duration: 16 mo CE by 2 nursery nurses with assistance of a PT and some house-mothers in a residential school for CP children; frequency not specified Duration: not specified	None	Case A – CP (type unspecified), IQ 70 Case B – CP (spastic quadriplegia and probable bulbar palsy), IQ 65 Both in the 'educationally subnormal' range of intelligence'	2	A=11 y B=9 y
1983 Titchener ²⁷	IV-W (2/7) Case series without controls	CE (not specified by whom) in a school for the physically handicapped; 1 hr/day Duration: 7 mo	None	CP (8) {spastic tetraplegia (1), athetosis (3), spastic quadriplegia (2), dystonic tetraplegia (1), road traffic accident (1)} Educational level: ESN(severe) (3), ESN(moderate) (3), 1 below average, 1 average	8	8-13 y
1989 Shields ²⁵	IV-W (1/7) Case series without controls	CE-based program by PT, OT, teacher, caregivers / nurse-aides, with input from speech therapist at a long term residential institution and special school for physically and intellectually disabled children; 3	None	CP (9) {spastic quadriplegia (7), athetosis (2)}, spina bifida + CP (1), chromosome anomalies (1), Lesch Nyhar syndrome (1) Cognitive level: not specified	12	3-6 y

AACPDM SYSTEMATIC REVIEWS OF EVIDENCE
 EXAMPLES OF SUMMARY TABLES III,IV, AND V

1993 Sigafoos ²⁶	IV-W (1/7) Case series without controls	task series/wk, each 45 min long. Duration: 1 y <i>Younger group:</i> CE by 1 Hungarian conductor at a primary school; 3 hr/day 5dy/wk	None	CP (4) {nonambulatory (3), Intellectual disability: mild (2), not specified (2)}	4	22- 48 mo
		<i>Older group:</i> CE by 2 Hungarian conductors in a.m. / 3 Hungarian conductors in p.m. in a separate classroom at a primary school; 6 hr/day, 5 dy/wk Duration: 6 wk	None	CP (5) {nonambulatory (3) walks with assistance (2) Intellectual disability: moderate (1), severe (1), not specified (3)}	5	63- 127 mo
1995 Coleman ¹⁶	II-M (4/7) Cohort study with concurrent control group	5 CE-based programmes, (4 with Hungarian conductor and therapists, 1 with only therapists); 1/2 dy 5dy/wk to 1/2 dy 5/14 dy Duration: 26 wk	4 centre-based early intervention programs using traditional approaches to therapy and special education; frequency not specified Duration: 26 wk	CP (20) {spastic diplegia (7), hemiplegia (1), spastic quadriplegia (11), athetosis (1)} Cognitive level: not specified	20 CE=9 Ctl=11	19- 69 mo
1995 Catanese ¹⁴	II-M (4/7) Cohort study with concurrent control group	General statement that CE based programmes staffed by Hungarian conductors, Australian trained	Individual physiotherapy programmes; frequency not specified Duration: 26 wk	CE: CP (17) {mild (5), moderate (11), severe (1)} Control: CP (17) {mild (5), moderate (7), severe (5)} Associated intellectual	34 CE=17 Ctl=17	4-7 y

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		therapists and teachers; frequency not specified Duration: 26 wk		disability: CE: mild (6), moderate (7), severe (4) Control: mild (6), moderate (7), severe (4)		
1995a Hur ²¹	III-W (2/7) Cohort study with historical control group	CE by British school teachers trained as conductors in the Birmingham Institute for Conductive Education; 'physical' programme =14.0 hr/wk (average), 'academic' programme = 4.0 hr/wk (average) ^b Duration: 2 y	Special education programs at special schools for children with physical handicaps; 'physical' programme =3.3 hr/wk (average), 'academic' programme = 8.0 hr/wk (average) Duration: 2 y	CE: CP (19) {mild (5), moderate (4), severe(10)} Control: CP (17) {mild (5), moderate (6), severe (6)} Cognitive level: CE: mean IQ = 83.5 Control: mean IQ = 85.1	36 CE=19 Ctl=17	5-6½ y
1995b Hur ²²	III-W (2/7) Cohort study with historical control group	CE by British school teachers trained as conductors in the Birmingham Institute for Conductive Education; 'physical' programme =14.0 hr/wk (average), 'academic' programme = 4.0 hr/wk (average) Duration: 2 y	Special education programs at special schools for children with physical handicaps; 'physical' programme =3.3 hr/wk (average), 'academic' programme = 8.0 hr/wk (average) Duration: 2 y	Mothers of 36 children with cerebral palsy (as described in 1995a Hur and 1997 Hur) CE: 19 mothers Control: 17 mothers	36 CE=19 Ctl=17	Not given

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1997 Hur ²⁰	III-W (2/7) Cohort study with historical control group	CE by British school teachers trained as conductors in the Birmingham Institute for Conductive Education; 'physical' programme =14.0 hr/wk (average), 'academic' programme = 4.0 hr/wk (average) Duration: 2 y	Special education programs at special schools for children with physical handicaps; 'physical' programme =3.3 hr/wk (average), 'academic' programme = 8.0 hr/wk (average) Duration: 2 y	CE: CP (19) {mild (5), moderate (4), severe(10)} Control: CP (17) {mild (5), moderate (6), severe (6)} Cognitive level: CE: mean IQ = 83.5 Control: mean IQ = 85.1	36 CE=19 Ctl=17	3½– 4½ y.																																				
1998 Reddihough ²⁴	I-S (6/7) Randomized controlled trial	R: CE-based programme with input from a Hungarian conductor at a children's hospital, mean frequency 2.8 hr/wk Duration: 6 mo	R: Individual therapy and playgroup with additional hours of therapy to match CE group; mean frequency 2.9 hr/wk Duration: 6 mo	<table border="0"> <tr> <td>R</td> <td>R</td> </tr> <tr> <td>CE (17)</td> <td>Control (17)</td> </tr> <tr> <td><u>mild</u></td> <td><u>mild</u></td> </tr> <tr> <td>diplegia 3</td> <td>diplegia 3</td> </tr> <tr> <td><u>moderate</u></td> <td><u>moderate</u></td> </tr> <tr> <td>diplegia 2</td> <td>diplegia 2</td> </tr> <tr> <td>quadriplegi</td> <td>quadriplegi</td> </tr> <tr> <td>a. 5</td> <td>a. 5</td> </tr> <tr> <td><u>severe</u></td> <td><u>severe</u></td> </tr> <tr> <td>diplegia 1</td> <td>diplegia 1</td> </tr> <tr> <td>quadriplegi</td> <td>quadriplegi</td> </tr> <tr> <td>a. 5</td> <td>a. 5</td> </tr> <tr> <td><u>not specified</u></td> <td><u>not specified</u></td> </tr> <tr> <td>ataxia 1</td> <td>ataxia 1</td> </tr> <tr> <td>Cog. level</td> <td>Cog. level</td> </tr> <tr> <td><u>normal</u> 11</td> <td><u>normal</u> 11</td> </tr> <tr> <td><u>impaired</u> 5</td> <td><u>impaired</u> 5</td> </tr> <tr> <td><u>unkown</u> 1</td> <td><u>unkown</u> 1</td> </tr> </table>	R	R	CE (17)	Control (17)	<u>mild</u>	<u>mild</u>	diplegia 3	diplegia 3	<u>moderate</u>	<u>moderate</u>	diplegia 2	diplegia 2	quadriplegi	quadriplegi	a. 5	a. 5	<u>severe</u>	<u>severe</u>	diplegia 1	diplegia 1	quadriplegi	quadriplegi	a. 5	a. 5	<u>not specified</u>	<u>not specified</u>	ataxia 1	ataxia 1	Cog. level	Cog. level	<u>normal</u> 11	<u>normal</u> 11	<u>impaired</u> 5	<u>impaired</u> 5	<u>unkown</u> 1	<u>unkown</u> 1	R: 34 CE=17 Ctl=17	12– 36 mo.
R	R																																									
CE (17)	Control (17)																																									
<u>mild</u>	<u>mild</u>																																									
diplegia 3	diplegia 3																																									
<u>moderate</u>	<u>moderate</u>																																									
diplegia 2	diplegia 2																																									
quadriplegi	quadriplegi																																									
a. 5	a. 5																																									
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	II-M (5/7) Non-randomized controlled trial	NR: CE-based programmes (not specified by whom); programmes staffed by Australian therapists and teachers with consultation provided by Hungarian conductors; mean frequency 3.2 hr/wk Duration: 6 mo	NR: traditional therapy programmes; mean frequency 2.2 hr/wk Duration: 6 mo	NR CE (15) <u>mild</u> diplegia 0 hemiplegia 2 quadriplegi a 1 <u>moderate</u> diplegia 1 quadriplegi a 2 <u>severe</u> diplegia 0 quadriplegi a. 9 Cog. level <u>normal</u> 6 <u>impaired</u> 9	NR Control (17) <u>mild</u> diplegia 3 hemiplegia 2 quadriplegi a 1 <u>moderate</u> diplegia 1 quadriplegi a 2 <u>severe</u> diplegia 1 quadriplegi a 7 Cog. level <u>normal</u> 10 <u>impaired</u> 7	NR: 32 CE=15 Ctl=17	12- 36 mo
1999 Bochner ¹³	V Part I: Case Series	Part I: School Project CE by 2 Hungarian conductors, 1 teacher, 1 aide, 2-3 volunteers 4 - 4.5 hr/day Duration: 2 y	None	CP Varying degrees of physical and intellectual impairment	6 ^c	12 y (n=5) 6 y (n=1)	
	IV-W (1/7) Part II: Case Series Without Controls	Part II: Preschool Project CE by 2 Hungarian conductors in a special school; 5.75 hr/day Duration: 1 y	None	CP Varying degrees of physical impairment Cognitive level: not specified	7	3-6 y	
2000 Lind ²³	V Descriptive case	CE by 4 Hungarian conductors at the	None	109 total respondents, CP (103), {spastic	109	2-12 y	

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series	Move and Walk Institute, children and families stayed at the institute the whole time Duration: 4 wk	diplegia (55), spastic quadriplegia (14), hemiplegia (8), ataxia (5), unspecified (21)},Others (6) {muscular diseases, spilidomia, and brain damage following surgery} Cognitive level: not specified
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CE, conductive education; CP, cerebral palsy; ESN, educationally subnormal; y, year; wk, weeks;dy, days; PT, physical therapist; OT, occupational therapist; hr, hours; mo, months; min, minutes; R, randomly assigned; NR, non-randomly assigned; Cog level, cognitive level; n, number.

^a The 626 clients all have CP

^b information about treatment frequency in Hur 1995a²¹, Hur 1995b²², and Hur 1997²⁰ derived from HMSO report²⁸

^c only 4 of the 6 children remained in the study for the full 2 years – the other 2 children were replaced in the second year.

Table IVa Conduct of Study (Table IVb would be completed, if necessary, in a similar manner)

<i>Study</i>	<i>Level/Quality</i>	1	2	3	4	5	6	7
1972a Heal ¹⁸	II-W (2/7) ^a	√					√	
1995 Coleman ¹⁶	II-W (4/7)			√	√	√	√	
1995 Catanese ¹⁴	II-W (4/7)			√	√	√	√	
1995a Hur ²¹	III-W (2/7)		√				√	
1995b Hur ²²	III-W (2/7)		√				√	
1997 Hur ²⁰	III-W (2/7)	√					√	
1998 Reddihough ²⁴ R:	I-S (6/7)	√		√	√	√	√	√
NR:	II-M(5/7)	√		√	√	√	√	

Conduct of the study is judged as Strong ('yes' score of 6 or 7), Moderate (score 5 or 4), or Weak (score ≤ 3)

11. Were inclusion and exclusion criteria of the study population well described and followed?

12. Was the intervention well described and was there adherence to the intervention assignment? (for 2-group designs, was the control exposure also well described?)

13. Were the measures used clearly described, valid and reliable for measuring the outcomes of interest?

14. Was the outcome assessor unaware of the intervention status of the participants (i.e. was there blind assessment)?

15. Did the authors conduct and report appropriate statistical evaluation including power calculations?

16. Were dropout/loss to follow-up reported and less than 20%? For 2-group designs, was dropout balanced?

17. Considering the potential within the study design, were appropriate methods for controlling confounding variables and limiting potential biases used?

OUTCOMES, MEASURES, AND RESULTS

Table V: Summary of studies: outcomes, measures, and results.

Study	Outcome of interest	Measure	Components of Health		
			Body Structure/s Body Functions	Activities and Participation	Contextual Factors
Catanese ¹⁴ 1995	Gross motor	VAB-BR-Video		<i>p</i> <.01 CE	
		Video Ratings		<i>p</i> <.03 CE	
	Fine Motor	VAB-BR-Video		<i>ns</i>	
		Video Ratings		<i>p</i> <.01 CE	
	Receptive language	VAB-BR-Video		<i>ns</i>	
		Video Ratings		<i>ns</i>	
		VAB-CR		<i>ns</i>	
	Expressive language	VAB-BR-Video		<i>ns</i>	
		Video Ratings		<i>ns</i>	
	Grooming	VAB-CR		<i>ns</i>	
		VAB-BR-Video		<i>ns</i>	
	Feeding	VAB-CR		<i>ns</i>	
		VAB-BR-Video		<i>ns</i>	
	Dressing	VAB-CR		<i>ns</i>	
		VAB-BR-Video		<i>ns</i>	
	Social Interaction	VAB-CR		<i>p</i> <.001 Ctl	
		VAB-BR-Video		<i>p</i> =.05 Ctl	
	Play	VAB-CR		<i>p</i> <.02 CE	
		VAB-BR-Video		<i>ns</i>	
	Toileting	VAB-CR		<i>ns</i>	
VAB-BR-Video			<i>ns</i>		
Parent/Family Problems	QRS-F modified			<i>p</i> <.05 CE	
	QRS-F modified			<i>ns</i>	
Pessimism	QRS-F modified				
	QRS-F modified				
Child Characteristics	QRS-F modified		<i>ns</i>		
	QRS-F modified		<i>p</i> =.01 CE		
ADL	Video Ratings		<i>ns</i>		
	Video Ratings		<i>ns</i>		
Compliance	Video Ratings		<i>ns</i>		
	Video Ratings		<i>ns</i>		
Cognitive Ability	CMMS		<i>p</i> =.005 Ctl		
	RDLS		<i>ns</i>		
	PPVT		<i>ns</i>		
	WPPSI (drawing and maze subtests)		<i>p</i> <.03 Ctl		
Cognitive and Physical Skills	WPPSI (drawing and maze subtests)				
	WPPSI (drawing and maze subtests)				

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	Numeracy skills	SB subtest	<i>ns</i>	
		DMT	<i>ns</i>	
Coleman ¹⁶ 1995	Gross motor	VAB-BR-Video		<i>ns</i>
	Fine motor	VAB-BR-Video		<i>ns</i>
	Receptive language	VAB-BR-Video		<i>ns</i>
		VAB CR		<i>ns</i>
	Expressive language	VAB-BR-Video		<i>ns</i>
		VAB CR		<i>ns</i>
	Grooming	VAB-BR-Video		<i>ns</i>
		VAB CR		<i>ns</i>
	Feeding	VAB-BR-Video		<i>ns</i>
		VAB CR		<i>ns</i>
	Organizational behavior	VAB CR		<i>ns</i>
	Dressing	VAB CR		<i>ns</i>
	Social Interaction	VAB CR		<i>p</i> =.004 CE
	Play	VAB CR		<i>ns</i>
	Toileting	VAB CR		<i>ns</i>
	Parent/Family	QRS-F		<i>ns</i>
	Problems	QRS-F		<i>ns</i>
	Pessimism	QRS-F		<i>ns</i>
Child Characteristics				
Reddihough ² ⁴ 1998	Cognitive	VAB-BR-Video	<i>ns</i>	
		VAB CR	<i>ns</i>	
	Feeding	VAB-BR-Video		<i>ns</i>
		VAB CR		<i>ns</i>
	Play	VAB-BR-Video		<i>ns</i>
		VAB CR		<i>ns</i>
	Expressive Language	VAB-BR-Video		<i>ns</i>
		VAB CR		<i>ns</i>
	Receptive Language	VAB-BR-Video		<i>ns</i>
		VAB CR		<i>ns</i>
	Gross Motor	VAB-BR-Video		<i>ns</i>
		GMFM: L&R (n=22)		<i>ns</i>
		Sitting (n=22)		<i>ns</i>
		C&K (n=22)		<i>ns</i>
	Standing (n=22)		<i>ns</i>	
	W&R (n=22)		<i>ns</i>	

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	Total score (n=22)		<i>ns</i>	
Fine motor	VAB-BR-Video		<i>ns</i>	
Organizational behavior	VAB CR		<i>p<.05 Ctl</i>	
	VAB CR		<i>ns</i>	
Dressing	VAB CR		<i>p<.05 CE</i>	
Grooming	VAB CR		<i>ns</i>	
Social	VAB-BR-Video		<i>ns</i>	
Toileting	QRS-F modified		<i>ns</i>	
Parent perceptions of coping	VAB-BR-Video			<i>ns</i>
Cognitive	RDLS	<i>ns</i>		
	VAB-BR-Video	<i>ns</i>		
Feeding	VAB CR		<i>ns</i>	
	VAB-BR-Video		<i>ns</i>	
Play	VAB CR		<i>ns</i>	
	VAB-BR-Video		<i>ns</i>	
Expressive Language	VAB CR		<i>ns</i>	
	VAB-BR-Video		<i>ns</i>	
Receptive Language	VAB CR		<i>ns</i>	
	VAB BR (video)		<i>ns</i>	
Gross Motor	GMFM: L&R (n=19)		<i>ns</i>	
	Sitting (n=19)		<i>p<.05 Ctl</i>	
	C&K (n=19)		<i>ns</i>	
	Standing (n=19)		<i>ns</i>	
	W&R (n=19)		<i>p<.05 Ctl</i>	
	Total score (n=19)		<i>ns</i>	
	VAB-BR-Video		<i>p<.05 Ctl</i>	
Fine motor	VAB-BR-Video		<i>ns</i>	
Organizational behavior	VAB CR			
	VAB CR			
Dressing	VAB CR		<i>ns</i>	
Grooming	VAB CR		<i>ns</i>	
Social	VAB CR		<i>ns</i>	
Toileting	QRS-F modified		<i>ns</i>	
Parent perceptions of coping				<i>ns</i>

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Abbreviations: CI, Clinical Improvement; *ns*, not significant; ECFAT, Eau-Claire Functional Abilities Test; WBSI, Wolfe-Bleuel Socialization Inventory; VLDS, Verbal Language Developmental Scale; PPVT, Peabody Picture Vocabulary Test; PIAT, Peabody Individual Achievement Test; VAB BR (video), Vulpe Assessment Battery – Behavior Rating (modified); VAB CR, Vulpe Assessment Battery – Caregiver Rating (modified); ADL, Activities of Daily Living; QRS-F Questionnaire on Resources and Stress (short form); CMMS, Columbia Mental Maturity Scale; RDLS, Reynell Developmental Language Scale, WPPSI, Weschler Pre-school Scale of Intelligence (revised); SB, Stanford Binet; DMT, Diagnostic Mathematical Task; CRT, Comprehensive Reading Test; MI, Malaise Inventory; VABS IE, Vineland Adaptive Behavior Scales Interview edition; VABS CE, Vineland Adaptive Behavior Scales Classroom edition; DP2 SHAS, Developmental Profile 2 Self-help Age scale; DP2 CAS, Developmental Profile 2 Communication Age scale; DP2 PAS, Developmental Profile 2 Physical Age scale; DP2 SAS, Developmental Profile 2 Social Age scale; GMFM, Gross Motor Function Measure; L&R, Lying and Rolling; C&K, Crawling and Kneeling; W&R, Walking and Running

² CE and Ctl indicate the group with significantly different result

³ Activities not described in enough detail to determine level of disablement, thus reduced to lower level of impairment

⁴ Statistics cannot be interpreted – incorrect assumption and use of Spearman's correlation coefficient

⁵ Outcome of interest not described in enough detail to assign a level of disablement

⁶ Mothers of children in CE group had significantly higher levels of satisfaction at baseline, end of yr 1 and end of yr 2 ($p < .01$).
Authors' attributed significant difference at baseline to mothers' 'initial faith' in CE program