



**Family Support for
Children with Disabilities**

**Guidelines for
Demonstrating Effectiveness**

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Alberta



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Family Support for Children with Disabilities

Guidelines for Demonstrating Effectiveness

Intent

The following guidelines are intended to assist in making informed, well-reasoned and fair decisions about whether an emerging or controversial intervention is based on practices, strategies and approaches that are demonstrated to be effective.

Background

The Family Support for Children with Disabilities (FSCD) Program is responsible for ensuring that services are being delivered according to provincial regulations and policy, and meeting the needs of families through best practices. When the purpose of the service is to intervene as early as possible and significantly improve the development of vulnerable children, the need for effective practice is essential.

The FSCD legislation provides for developmental and behavioural supports and specialized services. These supports and services are required by regulation to be based on established rehabilitative practices, strategies and approaches that are reasonable, least intrusive and demonstrated to be effective. The decision to approve or deny an emerging or controversial support or service that appears to hold the promise of making an improvement in the lives of children with disabilities and their families is a difficult one. Practices may be considered “established” if they are a) commonly accepted amongst members of the relevant professional community; b) supported by a strong theoretical rationale that describes the mechanisms through which the practice, strategy or approach will lead to clearly articulated functional outcomes; and c) supported by evidence of effectiveness.

Behavioural/developmental supports and specialized services based on established rehabilitative practices also adhere to the core principles described below.

❖ **Established rehabilitative practices respect the safety, well-being and dignity of the child and the family**

Established rehabilitative practices minimize the risk of both direct and indirect harm. Some interventions, though based on evidence of effectiveness, (e.g. punishment procedures) carry direct and obvious risks to the health, safety and dignity of the child. Other seemingly harmless interventions can place the parent and/or child at risk if they are overtaxing or inappropriate (e.g., not sensitive to individual differences). Another

type of indirect harm arises from lost opportunities to be involved in effective interventions or "typical" child and family experiences.

❖ **Established rehabilitative practices are family-centred**

Established rehabilitative practices recognize the parents/guardians as the most knowledgeable and important persons in a child's life and meaningfully involve them in service selection, planning and delivery. These practices are individualized, flexible and responsive, promoting the achievement of optimal child, parent and family outcomes.

❖ **Established Rehabilitative practices are evidence-based and evolving**

Established rehabilitative practices are the result of ongoing processes of scientific research, peer review and refinement. Increasingly rigorous levels of evidence are required to move a practice from novel and emerging to "established." In addition, a practice is only "established" for the population and situation in which it was studied and only as long as it is supported by current, credible evidence.

Overview and Organization

The guidelines in this document support informed decision making by the Director regarding the effectiveness of requested behavioural/developmental and/or specialized services that are unfamiliar to the program and/or where concerns regarding the intervention have been raised. The guidelines are organized into two sections: Description and Evidence.

It should be noted that while credible scientific evidence sets a foundation for effectiveness, situational factors including adequate implementation will have an impact on the effectiveness of the proposed practice and must also be considered when making decisions about appropriate services. Even when the effectiveness of a practice is supported in the literature and represents a desirable intervention option in terms of feasibility, there is no guarantee that a local service provider will implement the practice effectively.

Description

As part of the process for determining if a proposed service is appropriate, the practice must be clearly described with sufficient clarity and detail to evaluate the evidence and whether it adheres to the three core principles of established rehabilitative practice. The following elements of a proposed service must be adequately described.

1. The target population
2. Intended goals/objectives (are they meaningful, are they clearly stated)

3. Approaches or strategies used to achieve goals/objectives (is there enough detail provided to replicate what they do)
4. Logic or rationale regarding how the practice leads to intended outcomes (is the rationale consistent with accepted theories of human development, do they make common sense)
5. Research evidence that supports the effectiveness of the practice, strategy, or approach (is the proposed practice based on established rehabilitative practices with demonstrated effectiveness)

The next section regarding evidence is intended to clarify what is considered valid evidence as well as provide guidance for evaluating research evidence.

Evidence

Although the personal opinions of parents, providers and clinicians may be insightful, testimonial evidence must be verified through systematic investigation. The demonstration that an intervention is primarily responsible for a stated outcome requires objective testing that accounts for other plausible explanations. For this reason the most compelling evidence is empirically valid experimental and quasi-experimental research (Smith, et al., 2007).

Models of evidence-based practice apply hierarchies of research evidence. Typically, expert opinion is considered the lowest level on the hierarchy, followed by case studies, group designs that have shortcomings in addressing threats to internal validity, group designs that have a high degree of internal validity (such as true experiments and Randomized Control Trials), and then, systematic reviews (including meta-analyses) of well-designed studies at the highest level (Hunsley, 2007). Studies using similar designs can often vary in quality. For this reason it is necessary to examine the “scientific rigor” or the degree to which a study accounts for both the variables under investigation and factors that might undermine or “contaminate” the findings. Key questions when reviewing the quality of published research of various designs are provided in [Appendix A](#).

The level of evidence considered should be directly related to the significance of the decision. Decisions regarding the use of interventions that are invasive, potentially harmful, resource intensive or where claims of effectiveness are not in keeping with current literature require greater consideration. Similarly, decisions made on behalf of others, such as policy decisions, warrant a higher degree of certainty than that required for decisions that may affect only one individual and do not require the investment of substantial amounts of public resources.

Empirically valid evidence, for the purpose of demonstrating effectiveness includes the following:

- 1) Meta-analyses¹ or State of the Evidence Reviews² published in peer reviewed journal articles that summarize the primary research literature to date.
- 2) Primary research published in peer reviewed journal articles including:
 - a) Randomized comparison group design studies
 - b) Rigorous³ Quasi-experimental comparison group design studies
 - c) Rigorous Time-series designs, including single subject research⁴

Evidence not considered empirically valid for demonstrating intervention effectiveness includes the following:

- testimonials⁵
- program evaluations that do not meet the criteria defined above
- unpublished research studies, reports or case studies

Classifying practices based on available research evidence

Hierarchies are also applied when summarizing available scientific evidence regarding particular practices. According to one classification system (Simpson, 2005), a practice can be classified as either a:

- a) Scientifically based practice
- b) Promising practice
- c) Practice with limited supporting information, or
- d) Not a recommended practice.

¹ Meta-analyses use processes in which the results of multiple studies, examining the same practice, are averaged giving a higher degree of certainty than any single study on its own. High quality meta-analyses aggregate only high quality experimental and/or quasi-experimental studies.

² State of the evidence reviews summarize the research literature to date. Although some may use meta-analytic techniques this is not necessarily the case and the conclusions involve subjective interpretation.

³ The empirical strength of the evidence provided is not solely a function of the type of research method used. Studies differ in the rigour applied to controlling other conditions (threats to validity) that may account for findings.

⁴ Single Subject Research (SSR) includes time series and quasi-experimental designs in which the participant or participants serve as their own control through frequent (often continuous) measurement of interventions and outcomes across several phases. During these phases the researcher applies and/or withdraws one or more interventions. SSR begins with a pre-intervention or baseline phase. A functional relationship is established when the data demonstrate that predicted changes in outcome(s) co-vary with the manipulation of the intervention(s).

⁵ Testimonials are statements or declarations of a witness. Testimonials are often offered by parents, providers, and or clinical experts either in person or through other mediums such as written testimonials, television and radio including news programs, and or posted on websites.

Scientifically based practices: have significant and convincing systematic empirical support of efficacy and safety. The Ministry takes the position that for demonstration of a scientifically based practice⁶:

- ❖ Both the characteristics and the consequences of the practice are adequately described and measured
- ❖ The characteristics and the consequences of the practice are functionally related⁷
- ❖ The observation of this relationship has been replicated across studies
- ❖ Alternative explanations for the relevant relationships are examined.

This level of classification requires replicated randomized comparison group design studies or an accumulation of evidence from quasi-experimental design studies evaluated through a meta-analysis that demonstrate significant intervention effects on meaningful functional outcomes.

Promising Practices: appear to demonstrate some efficacy and utility for a particular population, even though the intervention requires additional scientific verification. The Ministry takes the position that for the demonstration of a promising practice:

- ❖ Both the characteristics and the consequences of the practice are adequately described and measured
- ❖ The characteristics and the consequences of the practice are functionally related
- ❖ The observation of this relationship has been replicated across independent studies

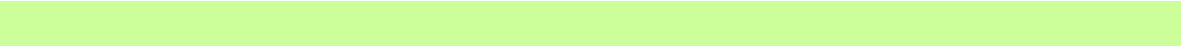
This level of classification requires multiple experimental and/or quasi-experimental design studies that demonstrate significant intervention effects on meaningful functional outcomes. Under situations where only single subject design studies are available, two or more of the published studies must meet all of the criteria applicable to single subject design studies outlined in [Appendix A](#).

Practices with limited supporting information: lack objective and convincing scientific support and have undetermined, possible, or potential utility and efficacy. The Ministry takes the position that for the demonstration of a practice with limited supporting information:

- ❖ Both the characteristics and the consequences of the practice are adequately described and measured
- ❖ The characteristics and the consequences of the practice are functionally related

⁶ List adapted from Dunst, Trivette, & Cutspec (2002).

⁷ It is not sufficient that an expected outcome occur after an intervention, as many factors, including a placebo effect, can account for change. What is required is that the mechanisms through which an intervention is presumed to operate are made explicit, are measured and are connected to changes in an expected manner, and the research design(s) have rendered other explanations for the change(s) implausible.



Practices with limited supporting information have at least one quasi-experimental design study but fail to convincingly demonstrate significant intervention effects on meaningful functional outcomes.

Not recommended practices: lack scientific support. The Ministry takes the position that practices are not recommended when:

- ❖ Either the characteristics or the consequences of the practice are not adequately described and measured
- ❖ The characteristics and the consequences of the practice have not been demonstrated to be functionally related

Practices that are scientifically based are considered to have demonstrated effectiveness for the purposes of the Family Support for Children with Disabilities FSCD Program. Promising practices that are based on a strong well articulated theory and widely accepted within the professional community may also be considered.

References

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Appendix A

Key Questions when Reviewing Published Research⁸ Designs

ALL DESIGNS

Study Description and Design

A1. Are participants, including pertinent demographic characteristics, selection criteria and procedures clearly described?	<input type="checkbox"/>
A2. Is the intervention described with sufficient detail to allow for replication ⁹ ?	<input type="checkbox"/>
A3. Is there systematic data describing the quality, intensity and settings of intervention delivery?	<input type="checkbox"/>
A4. Is the logic of how the intervention is supposed to affect outcomes clearly described?	<input type="checkbox"/>

Study's Collection of Outcome Data

B1. Is there satisfactory systematic evidence that the outcome measures are reliable – i.e., adequate retest and/or inter-rater reliability as appropriate?	<input type="checkbox"/>
B2. Is there satisfactory systematic evidence that the outcome measures are valid – i.e., adequate face, content, criterion (concurrent and/or predictive) and/or construct validity as appropriate?	<input type="checkbox"/>
B3. Are measures administered by someone that is qualified?	<input type="checkbox"/>

Study's Reporting of Results

C1. Does the study include results of all individuals that participated in both the baseline and intervention phases of the study?	<input type="checkbox"/>
C2. Does the study report on all outcomes measured, not just those with positive effects?	<input type="checkbox"/>
C3. Are all study limitations identified and discussed clearly?	<input type="checkbox"/>

SINGLE-SUBJECT RESEARCH DESIGN

B4.a Are outcomes measured sufficiently prior to the implementation of the intervention (baseline condition) to establish that the characteristic, behaviour or event targeted for change was stable or moving in the opposite direction to that predicted by the intervention?	<input type="checkbox"/>
B5.a Are outcomes measured sufficiently within and across comparison conditions i.e., shortly following the onset and/or withdrawal of the intervention, to allow for comparison of performance?	<input type="checkbox"/>
C4.a Have the results been replicated across a sufficient number of studies, researchers and participants? ¹⁰	<input type="checkbox"/>

⁸ Adapted from Horner, Carr, Halle, McGee, Odom, & Wolery (2005).

⁹ Information should include procedures, materials, and qualifications/training of individuals delivering the intervention.

¹⁰ Newsom and Hovanitz, (2006) suggest that replication across three studies involving two different researchers and nine participants are required to demonstrate the effectiveness of the intervention. Horner, et al., (2005) are more

GROUP RESEARCH DESIGNS¹¹

A5.b Does the study clearly describe how the intervention differed from what the control group received?	<input type="checkbox"/>
A6.b Were there any systematic differences between the intervention and control groups before the intervention on the following characteristics:	
a. Age	<input type="checkbox"/>
b. Gender	<input type="checkbox"/>
c. Socio-economic status	<input type="checkbox"/>
d. Severity of disability	<input type="checkbox"/>
e. Type and quantity of previous intervention programming	<input type="checkbox"/>
f. Child abilities associated with the outcomes investigated?	<input type="checkbox"/>
B4.b Are measures administered by someone who is unaware of group assignment (treatment or control)?	<input type="checkbox"/>
B5.b Are participants who drop out of the study reported and adequately accounted for in interpretation of findings and reported limitations?	
a. Is study drop out less than 25% of the original sample?	<input type="checkbox"/>
b. Is drop out the same for both the treatment and control group?	<input type="checkbox"/>
c. Are reasons for drop out reported? And if so, are they the same for all compared groups?	<input type="checkbox"/>
d. Did the study collect and report outcome data for those who dropped out?	<input type="checkbox"/>
B6.b Does the study report long-term outcomes following the intervention or lack thereof for all participants in all comparison groups including drop outs?	<input type="checkbox"/>
C4.b Does the study have a large enough sample(s) to provide adequate or reasonable power in testing for statistical significance?	<input type="checkbox"/>
C5.b Does the study report the size of the effect(s) and the statistical tests designed to describe the likelihood that the effect(s) occurred by chance?	<input type="checkbox"/>

conservative suggesting that clear evidence requires replication across five studies, involving three researchers and 20 participants.

¹¹ Adapted from U.S. Department of Education, Institute of Education Sciences, National Center for Education Evaluation and Regional Assistance (2003).